EPA Registration No. 3282-81 vol. 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB 6 2006

Ms. Liane Stockey
Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
PO Box 225
Parsippany, NJ 07054-0225

Dear Ms. Stockey:

Subject: Alternate Confidential Statements of Formula
d-Con® Ready Mix Baitbits
EPA Reg. No. 3282-81
d-Con® Bait Pellets II
EPA Reg. No. 3282-74
d-Con® Mouse Prufe II
EPA Reg. No. 3282-65
d-Con® Bait Pellets
EPA Reg. No. 3282-66
Your Applications Dated June 9, 2005

The alternate CSF's dated June 9, 2005 for the subject products have been reviewed and are acceptable. Please note that you cannot add any labeling statements indicating that these products contain a bittering agent without our approval. If you have any questions, please contact me at 703-308-6249.

Regards,

John Hebert
Insecticide-Rodenticide Branch
Registration Division (7505C)

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number: 307035

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
3282-81	John Hebert	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
d-CON® Ready Mix Baitbits	PM-7	

5. Name and Address of Applicant *(Include ZIP Code)*

Reckitt Benckiser Inc.
399 Interpace Parkway
Parsippany, NJ 07054-0225

☑ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No._____

Product Name_____

Section II

☑ Amendment - Explain Below
☐ Resubmission in response to Agency Letter dated_____.
☐ Notification - Explain below.
☐ Final printed labels in response to Agency Letter dated _____.
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submitting an Alternate CSF's for an Alternate Dye change (EPA approved dye per Criteria and Policy Notice 2164.2)
Formula #925-176

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* ***Certification must be submitted.***	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this applicaiton.)*

Name	Title	Telephone No. (Include Area Code)
Liane Stocky	Registration & Regulatory Compliance Assoc.	(973) 404-2716

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Liane Stocky	Registration & Regulatory Compliance Assoc.
4. Typed Name	**5. Date**
Liane Stocky	June 9, 2005

EPA Form 8570-1 (rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

Syngenta Crop Protection, Inc. Tel 336.632.6000
P.O. Box 18300
Greensboro, NC 27419-8300

syngenta

November 10, 2005

Mr. John Hebert, PM - 4B
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
1801 South Bell Street
Crystal Mall 2 – Room 266A
Arlington, VA 22202

SUBJECT: RECKITT BENCKISER INC.
AUTHORIZATION TO REFERENCE SYNGENTA'S
BRODIFACOUM DATA

Syngenta Crop Protection, Inc. (Syngenta) hereby authorizes the U.S. Environmental Protection Agency to refer to brodifacoum data as well efficacy data owned by Syngenta and on file as of November 10, 2005 for the limited purpose of evaluating the applications of Reckitt Benckiser Inc., to support registration of the following brodifacoum products:

D-Con Mouse Prufe II (EPA Reg. No. 3282-65)
D-Con Pellets Generation II (EPA Reg. No. 3282-66)
D-Con Bait Pellets II (EPA Reg. No. (3282-74)
D-Con Ready Mix Generation II (EPA Reg. No. 3282-81)

Syngenta holds proprietary rights to all brodifacoum data submitted to EPA under its current name, or previously submitted under the names of Ciba, Ciba-Geigy, Novartis, Sandoz, ICI and/or Zeneca.

This authorization is qualified to the extent, however, that: (1) the applicant or any other person except your Agency shall not have access to said data unless specifically authorized in writing by Syngenta, or when in the opinion of your Agency it is required in judicial administrative proceedings; (2) this authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any subsequent application submitted by the applicant; and (3) this authorization shall not be transferred by the applicant in any manner whatsoever without express prior consent of Syngenta (4) this authorization may be withdrawn by Syngenta at any time; and (5) this authorization shall be null and void if the applicant amends its registration to include any source of the subject active ingredient other than Syngenta Crop Protection, Inc.

If you have any questions concerning this letter of authorization, please contact me at 336.632.2062.

Sincerely,

Trina Brodie

Trina Brodie
Regulatory Specialist

cc: Liane Stocky – Reckitt Benckiser Inc.

Decision #: 358255

DATA PACKAGE BEAN SHEET

DP #: (321426)

Date: 07-Sep-2005

* * * Registration Information * * *

Registration: 3282-81 - D-CON READY MIXED GENERATION II

Company: 3282 - RECKITT BENCKISER INC.

Risk Manager: RM 07 - John Hebert - (703) 308-6249 Room# CM-2 213

Risk Manager Reviewer: Daniel Peacock DPEACOCK

Sent Date: _____ Calculated Due Date: 17-Dec-2005 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (305) DATA REQUIRED;TECHNICAL;

Ingredients: 112701, Brodifacoum(.005%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 07-Sep-2005 Due Back: _____

DP Ingredient: 112701, Brodifacoum

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: _____

	Assigned To	Date In	Date Out	
Organization:	RD / IRB			Last Possible Science Due Date: 20-Jul-2005
Team Name:				Science Due Date:
Reviewer Name:	[signature]	9/7/05	9/9/05	Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Bill,

Please review per my 8-29-2005 memo.

Thanks,

Dan Peacock, 305-5407

Bill Jacobs/DC/USEPA/US
08/31/2005 09:06 AM

To Dan Peacock/DC/USEPA/US@EPA
cc
bcc
Subject Re: memo, jackets coming 3282-65 +

Put it in as a 305. Whoever started in did not know what he/she was looking at, clearly.

Dan Peacock/DC/USEPA/US

Dan Peacock/DC/USEPA/US
08/31/2005 07:59 AM

To Bill Jacobs/DC/USEPA/US@EPA
cc John Hebert/DC/USEPA/US@EPA
Subject Re: memo, jackets coming 3282-65 +

Bill,

This is an issue that we will have to discuss with John as the situation has occurred in the past and will happen in the future.

- As you will notice, the actions were assigned a non-FFS action code (345), which translates into simple chemistry and administrative reviews.
- In this case, we need your input because we need to determine the status of the data supporting bittering agent formulations of these 4 products as well as your input into the policy question of whether we should change our past policy of not permitting bittering/non-bittering agent formulas under one product.
- Do we put a bean under 1) a 345 code, 2) a 305 code, which (I believe) the system allows, or 3) R34 code (with a charge the company)?

Thank You,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch

Tel: 703-305-5407
Fax: 703-305-6596
E-Mail: peacock.dan@epa.gov
Bill Jacobs/DC/USEPA/US

Bill Jacobs/DC/USEPA/US
08/30/2005 09:40 AM

To Dan Peacock/DC/USEPA/US@EPA
cc
Subject Re: memo, jackets coming 3282-65 +

I got the memo and the jackets. Where are the bean sheets?

Dan Peacock/DC/USEPA/US

Dan Peacock/DC/USEPA/US
08/29/2005 04:26 PM

To Bill Jacobs/DC/USEPA/US@EPA
cc
Subject memo, jackets coming 3282-65 +

Bill

See attachment

3282-65,-66,-74,-81, memo on 6-9-2005 amendments.wpd

Thank You,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Tel: 703-305-5407
Fax: 703-305-6596
E-Mail: peacock.dan@epa.gov

Questions/Possible Meeting Involving Two Recent D-Con Amendments for Alternate Formulas for 3282-65, -66, -74, -81
August 29, 2005

Subject 1. 11-29-2004 Alternate Formulas: Bittering Agent/Non-Bittering Agent
2. 06-09-2005 Alternate Formulas: Dye Concentration 1/Concentration 2

From Dan Peacock, Biologist
Insecticide-Rodenticide Branch

To William Jacobs, Vertebrate Biologist
Insecticide-Rodenticide Branch

Purpose The purpose of this memorandum is to receive your opinion about questions identified in my review of the past two amendments for these products and, if needed, to discuss these questions in a meeting with our team leader.

Amendment (bittering agent)

- On 7-5-2000, EPA previously had denied the company's request to have alternate (bittering agent/non-bittering agent) formulas under one product and requested the company to file an application for a new product.
- On 11-29-2004, the Co filed amendments requesting what the EPA had denied in July 2000.
- Ann Hanger approved the revised CSF on January 18, 2005.
- There were no efficacy reviews nor discussions of the pluses and minuses of approving the amendments and changing the policy.
- John Hebert approved the amendments on January 25, 2005.

Amendment (dyes) Company filed amendments for alternate CSFs for these products,
lowering the amount of dye but
increasing the certified limits (according to chemist note).
Company submitted MSDS.
Company gives no reason for needing this alternate CSF.

Action Code

- Joanne Miller assigned the amendments, a NON-Fee Action Code of 345.
- Such actions normally only require a simple chemistry/administrative review.

Questions I had the following questions about these amendments:

1. Were there acceptable efficacy data supporting the bittering agent alternate formula of November 29, 2004 and the earlier amendment denied in 2000?

Questions-continued

2. Do you think that it is advisable to have bittering agent and non-bittering formulas under a single registration number, a change in our previous policy?

3. Do you think it advisable to request the company to provide the reason for the lowered dye amounts in the products in the June amendments?

Meeting If your share my concerns with any of these questions, I suggest that we consider a meeting with our team leader, John Hebert, to discuss those concerns.

Questions If you have any questions about this memorandum, please contact me.

Dan Peacock, USB 512 MB Flash Drive 1, C:\Documents and Settings\dpeacock\Local Settings\Temp\notes6030C8\3282-65,-66,-74,-81, memo on 6-9-2005 amendments.wpd

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 16, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

LIANE STOCKY
RECKITT BENCKISER INC.
MORRIS CORPORATE CENTER IV
399 INTERPACE PARKWAY, PO Box 0225
PARSIPPANY, NJ 07054-0225

PRODUCT NAME: D-CON READY MIXED GENERATION II
COMPANY NAME: RECKITT BENCKISER INC.
OPP IDENTIFICATION NUMBER: 307035
EPA FILE SYMBOL: 3282-81
EPA RECEIPT DATE: 06/10/05

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 308-6249.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Questions/Possible Meeting Involving Two Recent D-Con Amendments for Alternate Formulas for 3282-65, -66, -74, -81

Subject 1. 11-29-2004 Alternate Formulas: Bittering Agent/Non-Bittering Agent
2. 06-09-2005 Alternate Formulas: Dye Concentration 1/Concentration 2

From Dan Peacock, Biologist
Insecticide-Rodenticide Branch D P Peacock 8/29/2005

To William Jacobs, Vertebrate Biologist
Insecticide-Rodenticide Branch

Purpose The purpose of this memorandum is to receive your opinion about questions identified in my review of the past two amendments for these products and, if needed, to discuss these questions in a meeting with our team leader.

Amendment (bittering agent)

- On 7-5-2000, EPA previously had denied the company's request to have alternate (bittering agent/non-bittering agent) formulas under one product and requested the company to file an application for a new product.
- On 11-29-2004, the Co filed amendments requesting what the EPA had denied in July 2000.
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lowering the amount of dye but
increasing the certified limits (according to chemist note).
Company submitted MSDS.
Company gives no reason for needing this alternate CSF.

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Questions I had the following questions about these amendments:

1. Were there acceptable efficacy data supporting the bittering agent alternate formula of November 29, 2004 and the earlier amendment denied in 2000?

Questions-continued

2. Do you think that it is advisable to have bittering agent and non-bittering formulas under a single registration number, a change in our previous policy?

3. Do you think it advisable to request the company to provide the reason for the lowered dye amounts in the products in the June amendments?

Meeting If your share my concerns with any of these questions, I suggest that we consider a meeting with our team leader, John Hebert, to discuss those concerns.

Questions If you have any questions about this memorandum, please contact me.

Dan Peacock, USB 512 MB Flash Drive 1, F:\1-7-2005 Backup\Dan's Office Work\A Flash Drive 1\Brodifacoum\3282-65,-66,-74,-81, memo on 6-9-2005 amendments.wpd

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 16, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

LIANE STOCKY
RECKITT BENCKISER INC.
MORRIS CORPORATE CENTER IV
399 INTERPACE PARKWAY, PO Box 0225
PARSIPPANY, NJ 07054-0225

PRODUCT NAME: D-CON MOUSE PRUFE II
COMPANY NAME: RECKITT BENCKISER INC.
EPA FILE SYMBOL: 3282-65
EPA RECEIPT DATE: 06/10/05

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 308-6249.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

IRB BRANCH REVIEW - TSS

Record Number(s)

3282-65: D321423
3282-66: D321424
3282-74: D321425
3282-81: D321426

IN 9/7/05 OUT 9/29/05

EFFICACY

FILE OR REG. NO. as above

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 6/10/05

DATE OF SUBMISSION 6/9/05, 6/10/05

DATE SUBMISSION ACCEPTED 9/7/05

TYPE PRODUCTS(S): I, D, H, F, N, R, x S

DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 07

PRODUCT NAME(S) d-CON Brodifacoum baits - see ~~xxxxx~~ next page for names

COMPANY NAME Reckitt Benckiser, Inc.

SUBMISSION PURPOSE have alternate formulation accepted

CHEMICAL & FORMULATION 0.005% Brodifacoum bait products

Efficacy Review: d-CON® MOUSE PRUFE II, 3282-65
d-CON PELLETS GENERATION II, 3282-66
d-CON® BAIT PELLETS II, 3282-74
d-CON READY MIXED GENERATION II, 3282-81
Reckitt Benckiser, Inc.
Wayne, NJ 07474

200.0 INTRODUCTION

THIS REVIEW DISCUSSES CONFIDENTIAL BUSINESS INFORMATION (CBI) SOME OF WHICH MAY BE UNKNOWN TO THE REGISTRANT OF THESE PRODUCTS. DO NOT DISCLOSE CBI TO UNAUTHORIZED THIRD PARTIES OR TO ANYONE LACKING APPROPRIATE CLEARANCES.

200.1 Uses

3282-65 is a 0.005% Brodifacoum dry bait in 1.5-oz or 3.0-oz wedge-shaped cardboard boxes conditionally registered

to control house mice in homes, industrial, commercial, agricultural and public buildings.

3282-66 is a 0.005% Brodifacoum dry bait sub-packaged in 3-oz bait trays conditionally registered

to control Norway Rats, Roof Rats, and House Mice in and around homes, industrial, commercial, agricultural and public buildings.... also ... in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.

3282-74 is a 0.005% Brodifacoum dry bait in 1-oz (28-g) placepacks conditionally registered

to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings.... also ... in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.

3282-81 is a 0.005% Brodifacoum dry bait in 3-oz bait trays conditionally registered

to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings.... also ... in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.

200.2 Background Information

For 3282-65, see efficacy reviews of 12/23/80, 6/5/81, 12/22/87, 8/1/88, 8/11/89, 6/7/90, 6/13/90, 7/11/90, 9/4/90, 3/19/91, 2/1/96, 5/27/99, 1/4/00, 7/23/01, 7/27/01, and 2/2/04, along with other information in this product's jacket. 3282-65 was registered on 11/6/81. Its current labels were "**ACCEPTED**" on 1/29/02. This product is considered to be a ready-to-use bait station that is not tamper-resistant. Consequently, the product's label is required to bear the text shown below.

THIS IS NOT A TAMPER-PROOF OR TAMPER-RESISTANT BAIT STATION. DO NOT USE THIS PRODUCT IN AREAS ACCESSIBLE TO CHILDREN, PETS, DOMESTIC ANIMALS, OR NONTARGET WILDLIFE. DO NOT USE THIS PRODUCT OUTDOORS.

For 3282-66, see efficacy reviews of 12/30/80, 6/5/81, 12/23/87, 7/15/88, 8/16/88, 12/29/88, 5/14/90, 7/16/90, 1/30/96, 1/12/98, 1/6/00, and 2/2/04, along with other information in this product's jacket. This product was registered on 11/18/81. Its current labels of record were was stamped "**ACCEPTED**" by IRB on 1/5/99.

For 3282-74, see efficacy reviews of 12/22/87, 8/1/88, 8/11/89, 11/30/89, 11/17/92, 4/12/93, 11/10/93, 12/15/94, 5/25/99, 1/7/00, 7/23/01, 7/27/01, 5/29/03, and 2/2/04, along with other information in the product's jacket. This product was registered on 1/16/86. Via a letter of 10/16/01, RB officially changed the name of this product from "d-CON LIM-N8 RAT KILLER" to "d-CON BAIT PELLETS II". RB's immediate predecessor in product ownership (Reckitt & Colman) originally used the latter name as an alternative brand name, having added it by

"Notification" on 5/25/93. The current labels of record for 3282-74 were "ACCEPTED with COMMENTS" by IRB on 6/30/03.

For 3282-81, see efficacy reviews of 1/18/89, 7/16/90, 10/15/90, 1/30/96, 5/25/99, 1/7/00, and 2/2/04, along with other information in this product's jacket. This product was registered on 2/1/89. Its "current" labeling was "ACCEPTED with COMMENTS" on 1/28/99. Reckitt and Colman (R&C), did not submit final printed labeling in response to EPA's letter of 1/28/99. Instead, R&C submitted new proposed revised labeling to which IRB objected.

See also the Reregistration Eligibility Decision (RED) for the Rodenticide Cluster (hereafter "Cluster RED") which EPA mailed to registrants of Brodifacoum products in August of 1998. The Cluster RED also pertained to pesticide products containing the active ingredients Bromadiolone, Bromethalin, Chlorophacinone, Diphacinone, and Pindone (a.k.a. "Pival"). On 2/2/04, I completed an efficacy review pertaining to materials submitted to support reregistration of all 4 of the d-Con Brodifacoum baits.

Among the provisions of the Cluster RED were "**Short-Term Risk Mitigation Measures**" ("**Phase One**" requirements), one of which was that baits registered for use in and around homes (and any other non-agricultural sites) had to be reformulated to contain an "**Indicator Dye and Bittering Agent**". Prior to the issuance of the Cluster RED, I argued against imposing the "**Indicator Dye and Bittering Agent**" requirements, for reasons elaborated below.

The Cluster RED also announced a "**Long-Term Risk Reduction**" ("**Phase Two**") strategy which was to consist chiefly of a search for "a safer technology" to be effected via the convening of a "Stakeholder group". I subsequently was on the panel of the "Stakeholder group", which formally was called the "Rodenticide Stakeholders Workgroup" (RSW). The RSW met in 5 sessions for a total of 6 days between 3/30/99 and 10/18/99. Among the other RSW panelists was Eileen Moyer of R&C (and subsequently of RB).

The first anticoagulants in the d-Con line of rodenticides were Warfarin products registered to the d-Con Company of Chicago, headed by Lee Ratner. In the late 1950's, the d-Con Company was sold to Sterling Drug Inc., which held some of the original d-Con Warfarin registrations (e.g., 3282-4) for about 30 years and was the initial registrant for the products discussed in this review. (If I remember correctly, Sterling was taken over by Eastman Kodak some time in the 1980's.)

Starting in 1990 or so, the corporate entities in charge of these products have morphed from Lehn and Fink, to R&C, and now to RB, with no change in company number. Over that period of time, many different people corresponded with EPA regarding these products; and there was a considerable lack of follow-through on the registrant's part regarding making required label changes, submitting final printed labels, etc. Such instances are evident from perusing the registration jackets for 3282-65, 3282-66, 3282-74, and 3282-81. As I have summarized the most egregious of the "communication" problems in prior efficacy reviews, I will not recount them here. However, I should note that the lack of consistent and appropriate follow-through by the registrant suggests that we should not accept formulation changes conditionally -- without the necessary supporting data -- and should leave nothing to chance with this registrant when it comes to labeling.

On January 24, 2005, IRB accepted revised Confidential Statements of Formula (CSFs) for 3282-65, 3282-66, 3282-74, and 3282-81. Dated "November 29, 2004", the new CSFs differ from prior CSFs of record for these products mainly through the addition of an alternate source of active ingredient and were accepted without efficacy or product chemistry reviews. As discussed below, the alternate source product contains the substance Denatonium Benzoate as well as other inert ingredients and, of course, Brodifacoum.

Denatonium Benzoate (trade name "Bitrex" for Macfarlan Smith, Ltd.) has an extremely bitter taste to adult humans. It has been used to denature ethanol and has been added to various toxic substances in hopes of deterring consumption of them by humans and pets. Congress recently was petitioned to require that Denatonium Benzoate (DB) be added to antifreeze used in the U.S. as a deterrent to dogs. (Antifreeze is both attractive and toxic to dogs and has been used nefariously to poison them. Accidental exposures also occur through coolant leakage.)

At times since 1947, DB and the related compound Denatonium Saccharide (trade name "RO•PEL") have been registered as active ingredients in pesticide products variously claimed to reduce browsing damage by deer and other cervids, to reduce damage to other types of plants by various types of mammals, and to deter dogs and other animals from chewing on various types of property and structures commonly found in homes and on farms.

The idea of using Denatonium Benzoate (DB) in Brodifacoum baits to limit to their being consumed by young children first was advanced to EPA in 1989 by ICI America's, Inc. (subsequently Zeneca, Inc., with its remaining Brodifacoum registrations now being owned by Syngenta Crop Protection, Inc.). ICI was aware of the need to retain palatability of baits to targeted rodents and, consequently, limited the DB level to 0.001% (10 ppm). That concentration was found to be unpleasant by adult human volunteers (company employees, Kaukeinen, pers. comm.) but was reported not to be deterrent to dogs and was not tested with children of poisoning prone age (Kaukeinen and Buckle, 1992, Proc: 15th Vert. Pest Conf., U. CA, Davis, 192-198).

In response to proposals by ICI and others subsequently, IRB allowed DB to be added to rodenticide baits provided that laboratory efficacy screening trials suggested the baits to be effective against Norway rats and house mice. That approach followed the general policy for any inert ingredient added to rodenticide baits. As with any other inert ingredient except those which are significantly toxic in their own right, it was left to the registrant's discretion whether to state on the product's label that DB was present in the bait. For the following reasons, registrants were not permitted to state on labels that DB made their products safer:

1. it is illegal to claim that any pesticide product is safe or comparatively safe [40 CFR §156.10(a)(5)(ix and x);

2. being a tastant, DB could not prevent oral exposures and, at best, could only limit the amount of bait ingested;

3. there was no compelling evidence that DB was protective of young children at concentrations (e.g., 10 ppm) that would allow baits to remain sufficiently palatable to targeted rodents;

4. there was no evidence that DB at such levels was protective of dogs, other pets, livestock, or nontarget wildlife; and

5. safety claims for DB likely would have detracted from label requirements to place baits in areas not accessible to children, pets, domestic animals, and nontargeted wildlife or in tamper-resistant bait stations.

Our policy with respect to adding dyes to baits is similar to that for other inert ingredients except that we allow dyes to be added to, or substituted into, baits if they previously have been screened for efficacy and found not to adversely effect bait palatability. That policy is based upon research conducted at the Terrestrial and Aquatic Biology Unit (TABU) which EPA formerly maintained on the grounds of the Agricultural Research Center in Beltsville, MD. TABU researchers screened 18 dyes for effects on palatability of a standard diet. Some of those dyes also were tested for effects on the efficacy of Warfarin baits formulated at the test facility.

Based upon the results of those studies, the Registration Division of OPP issued "Criteria & Policy Notice 2164.2" on 3/10/81. That notice identified 11 dyes that did not appear to adversely affect palatability of treated diet to house mice and 9 dyes (of that same 11) that also did not appear to adversely affect palatability of diet to Norway rats. The criterion used to decide that there were no adverse effects on palatability was $\geq$40% acceptance of treated diet vs. its placebo in a laboratory choice feeding trial (Palmateer, S.D. 1979. Effect of dyes in efficacy of commensal rodents. Unpublished report, TABU, Technical Services Division, Office of Pesticide Programs, U.S. EPA, 13 pp.).

Among the dyes that were found to affect palatability adversely were two (Rhodamine B and Malachite Green) that subsequently were listed among the 55 compounds on OPP's original list of inerts of concern and two others that commonly were used in field rodenticide baits prepared by California's agricultural commissioner's offices. Some of the effects of dyes on palatability were

severe. For example, Malachite Green (a.k.a "Brilliant Green" with 4 other synonyms) at 0.035% in diet reduced its acceptance to 3.6% and 5.2% in two trials in which Wistar strain rats were offered dye-treated diet vs. its placebo. Trials with concentrations of that dye as low as 0.0044% also were rejected by albino rats, but not to the extent that higher concentrations were. House mice also rejected diets treated with Malachite Green at concentrations of 0.0044% to 0.035%.

The foregoing discussions make it clear that adding dyes, bittering agents, or any other inert ingredients to baits is not a casual matter. As the bait must be eaten by target species if it is to be effective, any new inert ingredient must be assessed for its effects on palatability. Bait reformulation in general is not trivial and cannot be accomplished over night due to the need to test out the new product.

Nevertheless, the Cluster RED and also the Zinc Phosphide RED were issued with the "**Phase One**" requirements to reformulate, within an 8-month period, all rodenticide baits not strictly limited to agricultural applications. Although some baits registered at the time contained DB and many contained a dye, all would have had to be reformulated because none of them contained a substance shown to be an "**Indicator Dye**" according to the meanings for that the REDs implied for that expression. No substance that met the implied criteria for an indicator dye had been shown to exist in 1998. That circumstance persists today.

(Requiring that baits contain "a dye" rather than and "**Indicator Dye**" is something that could have -- and should have -- been effected via the Cluster RED. Any dye capable of coloring the bait would likely would have provided some of the advantages hypothesized for the "**Indicator Dye**", and most baits already had dyes in them. Baits lacking dyes could have had dyes from the list given in "Criteria and Policy Notice 2164.2" added to them, up to the concentration limits indicated in that notice, without the need for additional efficacy testing.)

It was known by the early 1990s that dyes could adversely affect the performance of rodenticide baits, that DB could only be used in baits at levels that would not adversely affect efficacy against target species, and that neither type of component could prevent exposures from occurring. At best, a bittering agent could limit the amount of bait ingested by children -- whether that happens remains unknown -- and a dye could show that exposures (e.g., oral and/or dermal) had occurred.

Although baits containing DB had been shown to pass laboratory efficacy trials and had been registered as a result, such results did not absolutely rule out adverse effects of that substance on bait efficacy. If rodents from an exposed population survived a baiting operation with a Bitrex-containing bait because they were especially sensitive to the taste of that compound, they would have become the founders of a rebounding population and, to the extent that the aversion was heritable, could have passed that tendency on to their descendants. If all baits available for use in non-agricultural markets contained the same substance and that substance that was aversive to "survivor" rats and their descendants, a strong selective pressure favoring DB rejectors would be exerted on baited populations; and it would be possible for all available baits to fail at once.

Reconsideration of the "**Phase One**" requirements was added to the list of issues before the RSW early in the course of its existence. That panel, which included government (Federal, State and municipal), rodenticide industry, pest control, medical, and public representation, recommended rescinding requirements to add the dye and bittering agent to baits. Essentially, the panel's recommendations were based on the issues mentioned in the two previous paragraphs, plus vehement objections to the bittering agent requirement by rodent control personnel from the City of Chicago who claimed that a Brodifacoum bait containing Bitrex was ineffective there because of that ingredient.

Those not supporting the bittering agent requirement included representatives from the American Association of Poison Control Centers and the Consumer Product Safety Commission. Earlier in the 1990s, those organizations had reviewed evidence for deterrent effects of DB on consumption of toxic materials. (See Jacobs, W. 2000, Proc. 19th Vertebrate Pest Conf., 19, 257-262, for elaboration on issues relating to indicator dye and bittering agent requirements.) With no clear evidence of protective value and some concerns about potential effects on efficacy, there seemed to be no basis for a firm requirement to add a bittering agent to rodenticide baits.

Product ingredient source information may be entitled to confidential treatment

Although the RSW recommended rescinding the "**Phase One**" requirements from the Cluster RED late in 1999 and, at the time, EPA agreed in principle with that recommendation, it was not until 2 years later that the decision on those matters was formally announced. That decision was to allow such substances to be added to baits but not to require them but to allow such substances to be in baits at the registrants' discretion. Essentially, the pre-RED policy was restored.

In November of 2004, the Natural Resources Defense Council (NRDC) and West Harlem Environmental Action (WHEA) sued EPA on grounds that the Agency had acted improperly in reversing the "**Phase One**" requirements (and that exposure incidents involving rodenticide baits and young children were increasing as a result of the reversals). In a summary judgment rendered on 8/7/05, the court essentially upheld EPA's rescission of the indicator dye requirement due to the fact that no such substance had been shown to exist but required EPA to revisit the bittering agent requirement (Rakoff, J.S. 2005, Memorandum Order in West Harlem Environmental Action and Natural Resources Defense Council, Inc. vs, EPA, U.S. District Court, Southern District of New York, August 7, 15 pp.).

IRB's acceptance of alternate Brodifacoum sources, with and without DB, for the d-Con bait products discussed in this review occurred during the early stages of the aforementioned lawsuit.

The actions currently before me pertain to amendment applications of 6/10/05 (3282-65) and 6/9/05 (3282-66, 3282-74, and 3282-81) in which RB announced that it was

> Submitting an Alternate CSF's [sic] for an Alternate Dye change (EPA approved dye per Criteria and Policy Notice 2164.2)

In routing those items to me on 9/7/05, IRB's Daniel Peacock referred to his memorandum of "*8/29/05*" (also to me) which posed the following questions:

1. Were there acceptable efficacy data supporting the bittering agent alternate formula of November 29, 2004 and the earlier amendment denied in 2000?

2. Do you think it is advisable to have bittering agent and non-bittering agent formulas under a single registration number, a change in our previous policy?

3. Do you think it advisable to request the company to provider the reason for the lowered dye amounts in the products in the June amendments?

The remainder of this review addresses those questions along with the recently submitted CSF's for RB's 4 Brodifacoum bait registrations.

201.0 DATA SUMMARY

201.1 Formulations

See discussions of these products' formulation histories prior to 2004 in the combined efficacy review of 2/2/04. The proposed CSF's considered in that review were dated 11/25/02. They listed the product that now is [redacted] as the source of active ingredient. It seems that the Product Reregistration Branch (PRB) prematurely communicated to RB that those CSFs were "accepted 1/07/03" (e.g., amendment form of 11/29/04 for 3282-65 signed by Paul R. Larson of RB). New CSF's for reregistered products can only be accepted by product registration branches, and are only accepted then when relevant efficacy issues are settled. Some of the efficacy studies submitted to support those CSFs ultimately were rejected, but I did not receive the package of materials to review until 1/13/03 (at which time I had a huge queue of other pending actions). The apparent acceptance of the CSF's of 11/25/02 by PRB in effect blessed a formulation change for 3282-74.

The CSF changes accepted on 1/24/05 were dated "November 29, 2004". Those CSF gave RB the option of continuing to use the [redacted]

Inert ingredient information may be entitled to confidential treatment

*Product ingredient source information may be entitled to confidential

[redacted]

Copies of the CSF's of 11/29/04 were included with RB's submissions of June, 2005.

The proposed CSFs submitted in June of 2005 are "Alternate Formulation" CSFs which list (in red ink) [redacted] The same CAS number is used for both (?) dyes, but their names are not identical. Different sources are identified for the dyes. To adjust for the lower concentration of dye claimed in the alternate formulation, the concentration claimed for [redacted] is increased.

To support the proposed "Alternate Formulation" applications, RB has included a "**MATERIAL SAFETY DATA SHEET**" (MSDS) for [redacted] That form identifies that dye as being in the "**Chemical Family**" called [redacted] and as having the CAS number [redacted]

[redacted]

which were listed on the CSFs of 11/29/04 (accepted on 1/24/05) and are listed again on the pending CSFs submitted this year.

Inert ingredient information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

A product chemist should be asked to look at the issue of identity between the two named dyes. If they really are the same material, then they should be listed as alternate sources on one CSF (per product) using the lower of the two claimed concentrations, if that is sufficient to color the bait thoroughly. If the two dye names refer to different entities, one should be selected as the dye to be used in the future, or they should be claimed on alternate and basic CSFs with any efficacy data needed to support the new dye being obtained.

[redacted] came to exist in 1994. In a letter of 6/23/94 sent prior to the product's registration (as [redacted] In fact, with the exception of certain dye substitutions, as discussed above, EPA did not accept alternate formulations for vertebrate pesticides in general. Thus, the separate-registrations policy with respect to DB was in line with the policy for any change of inert ingredients -- either make the new CSF the "Basic" one or obtain a new registration for the new formulation. That DB is a bitter compound reputed to be a taste deterrent simply made it all the more imperative that the same policy be followed for it. Even the dye substitutions that are allowed under a single registration number are granted only if there are data available which show or imply that the dye would not adversely affect bait efficacy.

The first applications for DB to be added to d-Con's Brodifacoum baits were submitted in 1999 (10/11/99 for 3282-65). R&C submitted "Alternate Formulation" CSFs for these products, with use [redacted] being one of the proposed differences between the "Basic" formulation then current and the proposed "Alternate Formulation". Those alternate formulations were hand-marked "*Acceptable*" by RD chemist Sami Malak but were not accepted by IRB. (Peacock hand-wrote "*NOT ACCEPTED*" on the CSFs of 10/6/99 for 3282-65 and 3282-81, but did not do so for those for 3282-66 and 3282-74. The CSF of 10/6/99 for 3282-74 subsequently was marked "SCANNED" on "SEP 3 2003"). Those "Alternate Formulation" CSFs were rejected because of the policy of not allowing alternate formulations for rodenticide baits. Data reports submitted to demonstrate effectiveness of alternate formulations also were rejected due to deficiencies in the reports, questions about laboratory conditions, and lack of documentation of the test materials used in the trials (see efficacy review of 1/4/00 for 3282-65, efficacy review of 1/6/00 for 3282-66, and efficacy reviews of 1/7/00 for 3282-74 and 3282-81).

Inert ingredient information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

There is no evidence in the jackets for 3282-65, 3282-66, 3282-74, or 3282-81 that the registrant attempted to resolve the data deficiencies or to replace [redacted] in the basic formulation for the product until submission of the CSFs of 11/29/04 listing [redacted] as alternate sources of Brodifacoum. With those applications, RB included various explanatory materials (e.g., the document entitled "***Updated Confidential Statement of Formula (CSF)* for d-CON®Mouse Prufe II, EPA Reg. 3282-65***"). Those documents discuss the ingredients listed on the pending CSF but do not mention Denatonium Benzoate or Bitrex and do not allude to the presence of a bittering agent in the alternative source product.

The applications were handled by a new (to IRB) employee, rather than Peacock, during the holiday season, when I was out of the office much of the time. During that period of time, I received several e-mails from and had some short conversations with the new employee about bittering agents in baits but evidently did not grasp exactly what was being requested by the applicant. It is clear that either the staff person or the product manager at least was aware that the [redacted] source product contained DB as the outgoing letters dated 1/24/05 included the sentence

> Please note that you cannot add any labeling statements indicating that these products contain a bittering agent without our approval.

Depending upon which source product was used to prepare the bait in the package, a label reference to the presence of Denatonium Benzoate in the product either would have been completely true or completely false.

201.2 Efficacy Data

No efficacy data were included with the application for the alternate formulation containing a different (?) dye, nor were any included with the amended CSFs dated 11/29/04. As noted above, there were no references to a bittering agent in those applications.

Previously, data that were submitted with a request to have a DB-containing "Alternate Formulation" were rejected (see efficacy reviews of 1/4/00, 1/6/00, and 1/7/00 for 3282-65, 3282-66, and 3282-74 and 3282-81, respectively). The efficacy reports submitted with RB's application for reregistration of these products did not include documentation sufficient to determine the compositions of the test materials used in the studies. The CSFs included with those applications claimed the product that now is [redacted] as the source of Brodifacoum and did not list DB as an intentionally added inert ingredient. Most of the efficacy studies submitted for product reregistration were unacceptable for one reason or another. A few of the reports were accepted as being applicable to whatever baits (formulations and particle sizes) ultimately were shown to have been the test materials used in the trials.

The "***Updated Confidential Statement of Formula (CSF)****" documents, letters, and application forms included with the amendment applications of 11/29/04 alleged certain virtues for the new CSFs (e.g., "tightening of certified limits for brodifacoum") but made no references to efficacy data specific to baits made with the [redacted] Nowhere in the application materials were mentioned the "Alternate Formulation" CSFs of 10/6/99 or the not-accepted efficacy studies said at that time to pertain to them.

The efficacy issues pertaining to [redacted] and/or to any of the dyes mentioned in Policy & Criteria Notice 2164.2. If [redacted] are identical, data supporting the current formulation would support the proposed "Alternate Formulation", and the two sources of dye, with the respective names that they give to it(?), could be listed on one CSF, if the concentration claimed for [redacted] corresponds to a dye "cleared" via Policy & Criteria Notice 2164.2, it could be used in a bait that already had passed efficacy tests up to the highest concentration for which the notice cleared it.

Inert ingredient information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

Criteria & Policy Notice 2164.2 lists 4 green dyes. The information provided in that document pertaining to green dyes is summarized below.

Dye	Color Index No.	Acceptable Dye Concentration in % Norway/Roof Rat	House Mouse
Fast Green FCF	42053	.035	.025
Monastral Green B	None Found	.030	.030
Zulu Green	None Found	.035	.035
Bromocresol Green	None Found	.035	.035

The Shaughnessy numbers for these dyes are identified below.

Fast Green FCF	911452
Monastral Green	
Monastral Fast Green G	911313
Monastral green GNX-G (CAS Reg. No. 1328-53-6)	911313
Zulu Green	none indicated
Bromocresol Green	none indicated

[redacted] would be covered by the data from Palmateer (1979) as reflected in Policy & Criteria Notice 2164.2 as well as by any efficacy data accepted as pertaining to an otherwise similar d-Con formulation containing [redacted] If not, efficacy data on a bait containing [redacted]" would be needed.

It is clear from correspondence included in RB's submissions of June, 2005, that the company had been made aware of Policy & Criteria Notice 2164.2 (via a FAX of 3/15/05 by IRB's Geraldine McCann). RB clearly considers [redacted] to be the same thing as [redacted] and, therefore, to be covered by the notice up to a concentration of [redacted] in baits claimed to control commensal rodents. As much is indicated in the June, 2005, letters from RB's Liane Stocky as well as on the similarly dated amendment application forms signed by Stocky.

The issue is simpler with respect to the bittering agent. Efficacy data are needed on d-Con Brodifacoum baits made from [redacted] if that source of Brodifacoum is to (continue to) be used in d-Con baits. [redacted]0 either must completely replace [redacted] as the source of Brodifacoum in 3282-65, 3282-66, 3282-74, and 3282-81; or d-Con must register new bait products claiming [redacted] as the source of active ingredient or drop [redacted] as a source completely. In light of the summary judgment in the NRDC-WHEA matter, RB's safer bet might be to go with [redacted] as the source product, although they might have to enhance the rest of the formulation(s) to compensate for DB.

In the early 1990's, John Domanski, a consultant on the d-Con line at the time, argued before me that evidence supporting the protective value of Bitrex in baits or any other agent was equivocal. Although such still seems to be the case, the idea that the bittering agent is protective clearly is politically accessible.

Due to their dominance on the over-the-counter rodenticide market, especially in drug stores and supermarkets, d-Con baits are likely to predominate in terms of numbers of reported exposure incidents involving young children and household pets. That was true when the d-Con baits being sold (3282-4, 3282-15, 3282-9) contained Warfarin (Jacobs, W. 1990. Rodenticide bait stations: major findings from public hearings and other investigations, ms., IRB/RD/EPA, 71 pp.) and such almost certainly is the case now with the d-Con Brodifacoum product line. Eating the same

Inert ingredient information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

amount of a 0.005% Brodifacoum bait is likely to be worse for a vertebrate organism (possibly excepting pigs) than if the bait were 0.025% Warfarin (or 0.054% for 3282-9). Would lacing the Brodifacoum baits with DB at 10 ppm make up the difference vs. Warfarin in potential hazard to small children? I doubt it. One Vitamin K_1 i.p. shot is apt to be all that is needed for a symptomatic (e.g., elevated prothrombin time) case with Warfarin. Repeated i.p. administrations of the same antidote likely would be needed in a symptomatic Brodifacoum case.

In light of the foregoing discussions, I can now offer short answers to the questions posed in Peacock's memorandum of 8/29/05. Those answers appear below each of the questions.

1. Were there acceptable efficacy data supporting the bittering agent alternate formula of November 29, 2004 and the earlier amendment denied in 2000?

No. The efficacy data submitted in support of the CSFs of 10/6/99 were not accepted at that time. New data do not seem to have been submitted, and no efforts to rehabilitate the original studies are apparent.

2. Do you think it is advisable to have bittering agent and non-bittering agent formulas under a single registration number, a change in our previous policy?

No.

3. Do you think it advisable to request the company to provider the reason for the lowered dye amounts in the products in the June amendments?

No. RB makes it clear why it selected the dye concentrations that it proposed to use: to have the dye accepted without the need for additional efficacy studies. Policy & Criteria Notice 2164.2 sets an upper limit on the concentration of the dye that RB claims to be using at [redacted]. It is a separate issue whether the dye selected marks the bait sufficiently well. As the "**Indicator Dye**" requirement is a dead issue, we would have to pursue anew the notion of requiring dyes, "indicator" or not, to be added to commensal rodenticide baits.

202.0 CONCLUSIONS

1. If the registrant's belief that "[redacted] is the same thing as [redacted]" is correct, no new efficacy data would be needed to support addition, or substitution, of "[redacted] into a bait at nominal concentrations up to [redacted] provided that

   a. the original bait formulation was adequately supported by efficacy data, and that

   b. no other changes had been made to the formulation along with the dye substitution that might adversely affect efficacy.

   Whether the [redacted] have been assigned all apply to the same substance should be determined by a qualified product chemist. If more than one substance is subsumed under those numbers, it is possible that the different substances would affect bait palatability differently.

2. If the two dyes discussed under item 1. are found to be identical, they both could be claimed for the same product. If they are identical, they could be claimed on a single Confidential Statement of Formula (CSF), per product, if the nominal concentration claimed for [redacted] If the different concentrations claimed for the two names are to be retained, then CSF's for "Basic" and "Alternate" would be needed

3. Use of either [redacted] as Brodifacoum source products in 3282-65, 3282-66, 3282-74, and 3282-81 should not have been accepted. As [redacted] contains the bittering agent Denatonium Benzoate, baits made from it possibly would not be accepted as well as otherwise identical baits made from [redacted]. The historical policy of not requiring alternate formulations for rodenticide baits should be applied to the use of concentrate source

Product ingredient source information may be entitled to confidential treatment

products that come with and without Denatonium Benzoate in them. That substance might affect bait efficacy and usually is claimed on product labels when it is present in the bait. A label claiming presence of Denatonium Benzoate would misbrand a bait made from the [redacted], unless the bittering agent were added separately. Separate addition of DB is not claimed on these products' Confidential Statements of Formula (CSFs) dated November 29, 2004.

The primary appropriate options for Reckitt Benckiser would be to:

a. replace [redacted] as the only source product for Brodifacoum in 3282-65, 3282-66, 3282-74, and 3282-81;

b. use [redacted] as the sole source of Brodifacoum in those products and have them not contain Denatonium Benzoate;

If option a. were selected, the company would have to provide new efficacy data on each distinct bait (formulation and particle size).

If option b. were selected, the company could rely on any existing efficacy data that support the products (e.g., see efficacy review of February 2, 2004) and fill in any data gaps with new or rehabilitated studies.

If the company wanted the option of using either concentrate, separate registrations could be obtained for products containing one of the concentrates with the other being used in the products already registered (i.e., 3282-65, 3282-66, 3282-74, and 3282-81). Clearly, the company also could use the [redacted] in one or more of these products and use [redacted] in the others. Whatever option is selected, the efficacy of the baits that contain Denatonium Benzoate would have to be established.

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
September 29, 2005

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 24, 2005

Mr. Paul Larson
Reckitt Benckiser, Inc.
399 Interpace Parkway
Parsippany, NJ 07054-0225

Dear Mr. Larson:

Subject: Revised Confidential Statement of Formulas (Brodifacoum)
EPA Reg. Nos. 3282-65, 3282-66, 3282-74, and 3282-81
Your Submissions Dated November 29, 2004

Your revised Confidential Statement of Formulas (CSFs) dated November 29, 2004 for EPA Reg. Nos. 3282-65, 3282-66, 3282-74, and 3282-81 are acceptable. Please note that you cannot add any labeling statements indicating that these products contain a bittering agent without our approval. If you have any questions, please contact Ann Hanger at (703) 306-0395 or hanger.ann@epa.gov.

Regards,

John Hebert
Product Manager 7
Insecticide/Rodenticide Branch
Registration Division (7505C)

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number: 295815

Application for Pesticide - Section I

1. Company/Product Number: 3282-81
2. EPA Product Manager: John Hebert
3. Proposed Classification: ☑ None ☐ Restricted
4. Company/Product (Name): *d-CON® Ready Mixed Baitbits*
   PM#: PM-7
5. Name and Address of Applicant *(Include ZIP Code)*:
   Reckitt Benckiser Inc.
   399 Interpace Parkway
   Parsippany, NJ 07054-0225
   ☑ *Check if this is a new address*
   COADR previously notified & PPIS updated.
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No._____
   Product Name_____

Section II

☑ Amendment - Explain Below
☐ Resubmission in response to Agency Letter dated_____.
☐ Notification - Explain below.
☐ Final printed labels in response to Agency Letter dated _____.
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Change of primary product name from d-CON® Ready Mixed Generation II to d-CON® Ready Mixed Baitbits.
2. Update of CSF including current RB address in Parsippany, NJ (Box 1.), [redacted] (10.,12.). Slight tightening of certified limits for brodifacoum and should be considered appropriate by the Agency. No changes in the nominal concentrations amounts and certified limits for the other components (13.a., b.; 14.a., b.) from previous CSF dated 11/25/02 -- approved 1/07/03. Updating of supplier information to reflect corporate changes and/or different locations (addresses) -- same sources.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	

* ***Certification must be submitted.***

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) of Retail Container
5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this applicaiton.)*

Name	Title	Telephone No. (Include Area Code)
Paul R. Larson	Mgr, Registration & Regulatory Compliance	(973) 404-2716

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Paul R. Larson	Mgr, Registration & Regulatory Compliance	
4. Typed Name	5. Date	
Paul R. Larson	November 29, 2004	

EPA Form 8570-1 (rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

Product ingredient source information may be entitled to confidential treatment

RECKITT BENCKISER

November 29, 2004

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

Attention: John Hebert, PM-7

Ref.: **d-CON® Ready Mixed Baitbits**
- EPA Reg. No.: 3282-81
- OPP ID No.: 295815
- Updated Confidential Statement of Formula (CSF)

Dear Mr. Hebert:

Reckitt Benckiser is submitting an amendment application for EPA Reg. No. 3282-81 to:

- Change the primary product name from **d-CON® Ready Mixed Generation II** to **d-CON® Ready Mixed Baitbits**.
- Update the Confidential Statement of Formula (CSF). Details can be found on the following page.

The enclosed documents support this registration action:

1. EPA Application of Pesticide Registration, Form 8570-1, OPP ID No. 295815
2. Two (2) copies of updated Confidential Statement of Formula, Form 8570-4, dated November 29, 2004, and approved by Agency on 1/07/03 (Product Chemistry Review).
3. One (1) copy of the previous CSF dated November 25, 2002 and submitted in response to RED.
4. EPA Formulator's Exemption Statement, Form 8570-27

Thank you for your prompt assistance with this registration action. If you have any questions, please contact me at (973) 404-2716 or via e-mail at paul.larson@reckittbenckiser.com

Sincerely,

Paul R. Larson
Manager, Regulatory & Registration Compliance

d-CON® is a registered trademark of Reckitt Benckiser Inc

RECKITT BENCKISER INC.
1655 Valley Road, P.O. Box 943, Wayne, NJ 07474-0943
TEL: (973)-633-3600 FAX: (973)-633-3633

RBI/RCC/PRL-112904

*** Contains Confidential Business Information ***

Updated Confidential Statement of Formula (CSF)* for d-CON® Ready Mixed Baitbits, EPA Reg. 3282-81

REGISTRANT ADDRESS CHANGE: Current Parsippany address is noted in Box 1. Change of address (COADR) previously notified for EPA Co. No. 3282 and currently reflected in PPIS.

GENERAL NOTE: [redacted]

All four **d-CON®** end-use registrations (EPA Reg. No. 3282-65, -66, -74, - 81) have the same formula (4-PA-165).

[redacted]

Brodifacoum

- No change in supplier or nominal concentration. Slight narrowing of certified limits.
- [redacted]

[redacted]

* * Previous CSF dated November 25, 2002 submitted in response to RED; EPA Product Chemistry Review, 7/JAN/2003. p.2., 3. *"The submitted CSF, a basic formulation dated 25/NOV/02, has been filled out completely and correctly. ... **The CSF is acceptable.**".*

[redacted]

*** Certified limits consistent with 40 CFR 158.175 (b)(2).

d-CON® is a registered trademark of Reckitt Benckiser Inc.

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Form Approved. OMB No. 2070-0060. Approval Expires 5-31-98.

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Reckitt Benckiser Inc. 399 Interpace Parkway Parsippany, NJ 07054-0225	3828-61
	Product Name d-CON® Ready Mixed Beitbits
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* November 29, 2004

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Brodifacoum [redacted])
[3-[3-(4'-bromo[1,1'-biphenyl][4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one]

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ **(A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).**

OR

☐ **(B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.**

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Brodifacoum	[redacted]	

Signature	Name and Title	Date
Paul R. Larson	Paul R. Larson, Mgr., Regist. & Regul. Compliance	11/29/2004

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

★ U.S. GPO: 1996-388-820/20413

July 5, 2000

305 5-571293
13

306 5-576327
13

Reckitt & Colman
1655 Valley Road
P.O. Box 943
Wayne, NJ 07474-0943

Attention: Mr. Sean McNear

Subject D-Con Ready Mix Generation
EPA Reg. No. 3282-81
Review of Data to Support Alternate Formula
Your submissions of October 12, 1999, and February 8, 2000

In the above submissions, you submitted product chemistry and effectiveness data to support an Alternate Formula containing Bitrex. While such a formula would need its own registration, we have reviewed the data to determine if they would be acceptable. Our detailed comments follow.

Chemistry data The chemistry data were acceptable except for the storage stability data (MRID No. 450377-01) for the following reasons:

1. After one year, the amount of active ingredient was less than the lower certified limit. This reduction in active ingredient would not likely affect efficacy. However, it could cause enforcement problems if EPA picked up a sample and found the amount of active to be lower than the lower certified limit.

2. The product is a pulverized version of another product. You reported identical results for both products. Was a study actual conducted on this product?

Review of CSF

Your Confidential Statement of Formula (CSF) for an Alternate Formulation, dated October 6, 1999, was unacceptable for the following reason. Except for a limited range of approved dye substitutions, we do not permit alternate formulations for rodenticide baits. We do not permit "with Bitrex" and "without Bitrex" formulations under a single registration number. You must either

1. replace the current formulation of 3282-81 with the new Bitrex-containing formulation or

2. apply for a new registration for the Bitrex-containing formulation.

Comparing your proposed revised Confidential Statement of Formula (CSF) of October 6, 1999, with the current CSF of record for 3282-81 reveals that many modifications to the formulation are proposed which are unrelated to the proposed addition of Bitrex.

Effectiveness data

The rat placepack-penetration study (MRID No. 449496-03) is not acceptable for the following reasons:

1. The testing facility's failed to provide an adequate amount of challenge diet at the onset of the bait-exposure period. This deficiency biased the test in favor of the product as about 5 times as much bait as challenge diet was available to rats at the beginning of the test.

2. The description of test material as a pelleted bait in a placepack would seem to make the study irrelevant in any case to 3282-81, which is supposed to consist of pulverized bait (formerly pelletized) in bait trays.

3. Other problems with this study include the failure to report raw data, failure to control the test environment (which was always too dry and usually too cold), and procedural irregularities involving the handling of animals.

4. The test material should not have been frozen prior to use because people who retail and buy rat-and-mouse baits are neither instructed nor expected to freeze baits until it is time to use them.

Effectiveness data-continued

5. The relevance of this study to the proposed new formulation is not established in the bioassay report, which does not mention Bitrex and does not identify a batch number for the test material. A batch number mentioned in the report of analysis is not mentioned in the report for the bioassay and probably was assigned by the testing facility rather than the formulator.

The mouse placepack-penetration study (MRID No. 449496-03) is not acceptable at this time for the following reasons:

1. Problems with this study include the failure to report raw data, failure to control the test environment (which was always too dry and usually too cold), and procedural irregularities involving the handling of animals.

2. The test material should not have been frozen prior to use because people who retail and buy rat-and-mouse baits are neither instructed nor expected to freeze baits until it is time to use them. If raw data are provided, we will reconsider this study.

3. The description of test material as a pelleted bait in a placepack would seem to make the study irrelevant in any case to 3282-81, which is supposed to consist of pulverized bait (formerly pelletized) in bait trays.

4. The relevance of this study to the proposed new formulation for 3282-81 (or any of your other products) is not established in the bioassay report, which does not mention Bitrex and does not identify a batch number for the test material. The batch number mentioned in the report of analysis is not mentioned in the report for the bioassay and probably was assigned by the testing facility rather than the formulator. Without appropriate documentation, we cannot be sure to what formulation this study applies.

Status of revised labeling

A review of the administrative record for this product revealed that your company has failed to respond to our July 1, 1999, letter that required submission of revised labeling on an expedited basis. The labeling problems mentioned in that letter were originally raised in communications from at least 1996. This item needs your immediate attention.

EPA Contact If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock.dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Letter Filed A:\3282-81.wpdJune 30, 2000

IRB BRANCH REVIEW - TSS

Record Number(s)

D261162

IN 12/8/99 OUT 1/7/00

EFFICACY

FILE OR REG. NO. 3282-81

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 10/14/99

DATE OF SUBMISSION 10/12/99

DATE SUBMISSION ACCEPTED 12/8/99

TYPE PRODUCTS(S): I, D, H, F, N, R, S

DATA ACCESSION NO(S). 449496-03 (rats), 449496-02 (mice)

PRODUCT MGR. NO. 04

PRODUCT NAME(S) d-CON READY MIXED GENERATION II

COMPANY NAME Reckitt & Colman, Inc.

SUBMISSION PURPOSE request "alternate formulation"

CHEMICAL & FORMULATION 0.005% Brodifacoum crushed-pellets dry bait

Efficacy Review: d-CON READY MIXED GENERATION II, 3282-81
Reckitt & Colman Company Inc.
Montvale, NJ 07645-1575

200.0 INTRODUCTION

200.1 Uses

3282-81 is a 0.005% Brodifacoum dry bait in 3-oz bait trays conditionally registered to control Norway rats, roof rats, and house mice

> "in and around homes, industrial, commercial, agricultural and public buildings ... [and] in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings."

200.2 Background Information

See efficacy reviews of 1/18/89, 7/16/90, 10/15/90, 1/30/96, and 5/25/99, along with other information in this product's jacket. This product was initially registered on 2/1/89. "Current" labeling was "ACCEPTED with COMMENTS" on 1/28/99. Reckitt and Colman (R&C) did not submit final printed labeling in response to EPA's letter of 1/28/99. Instead, R&C submitted new proposed revised labeling to which IRB has objected.

In the efficacy review of 5/25/99, I noted the company's past delinquencies in properly labeling this and its other rodenticide products and commented extensively on proposed revised labeling submitted on 3/10/99. Although slightly modified, these comments were passed on to R&C via IRB's letter of 7/1/99. R&C was given 30 days to respond or have the product subject to cancellation proceedings.

By or before 9/27/99, a Patricia Sheehy of R&C contacted Grace Robiou of IRB claiming that the letter of 7/1/99 did not get to her until August, although I had notes to the effect that Sheehy had inquired of Robiou on 7/14/99 about using up old labels for this and two other d-Con products. On 9/28/99, IRB granted R&C another 75 days ("from the date of receipt of this notice"). That period of time should have expired more than two weeks ago.

The label comments in the efficacy review of 5/25/99 pertained primarily to proposed promotional statements and the use of graphics on labels. There also was a proposal to modify the "**APPLICATION DIRECTIONS:**" subsection of the "**DIRECTIONS FOR USE**" in a way which would have directed placement of 3 ounces of unprotected bait at 8- to 12-foot intervals for the purpose of controlling house mice. In the efficacy review of 5/25/99, I noted:

The new text seems to negate the bait station requirements which appear elsewhere on the label and reads like a prescription for exposing young children and dogs of all ages to Brodifacoum. Not only does the proposed new text imply that the bait placements may be unprotected, each of these placements would consist of 3 oz. of bait rather than the typical 1/4-1/2 oz.

d-CON baits predominate in the over-the-counter rodenticide market in the U.S. and, consequently, also are implicated in the greatest numbers of exposure incidents involving young children. Adopting the proposed text might have ensured continuing domination in the latter category regardless of whether current sales trends were maintained.

The promotional claims issues boiled down to proposed statements which were counter to regulatory prohibitions against making "false or misleading" statements in pesticide labeling.

The graphics issues pertained to depictions traditionally used for this product and 3282-66 regarding how the product should be used. Many of the illustrations convey messages which are inconsistent with required label text and responsible use. The graphics issue has been raised with this company regarding this product in letters going back at least as far as 2/1/96. In the efficacy review of 5/25/99, I disagreed sharply with R&C's characterization of the impact of the graphics traditionally used, as it was presented in a letter of 3/10/99 from Bob Fellows.

This review discusses portions of R&C's submission of 10/12/98 for 3282-81. The materials routed to me include a cover letter, "Administrative Materials" including an amendment form dated 10/11/99 and a Confidential Statement of Formula (CSF) dated 10/6/99, and reports of two laboratory efficacy studies. In the cover letter, Sean McNear states that R&C proposes "an alternate formulation amendment" for this product "to incorporate the ingredient Bitrex". McNear's letter does not mention labeling.

R&C's decision to propose to include Bitrex in the formulation of 3282-81 probably was influenced by the Rodenticide Cluster RED, which was mailed by SRRD on 8/3/98 (and dated "July 1998"). That RED included "Phase 1" requirements for reformulation of all rodenticide baits, except those "used exclusively at agricultural sites", to include an "**Indicator Dye and Bittering Agent**". Whatever the impetus, we do not permit "with-and-without-Bitrex" alternate formulations for rodenticide baits.

Bitrex (Denatonium Benzoate) is a substance that tastes extremely bitter to humans but appears to be not quite as aversive to other mammals. In the late 1980's, its use as an adulterant of rodenticide baits first was proposed to us. We agreed that the substance could be added as long as it were demonstrated that the new formulation did not adversely affect the performance of the bait in laboratory efficacy tests. We did not require demonstrations that the Bitrex-containing baits worked under field conditions because of the expense of such tests and the fact that we did not require field tests for other formulation changes for "old-chemical" rodenticide active ingredients. Because Bitrex could possibly have adversely affected efficacy in actual use if not in the laboratory, because there were potential label changes associated with inclusion of Bitrex, and because of a traditional policy against alternate formulations for rodenticide baits, we did not permit Bitrex to be added in alternate formulations. (The only alternate formulations permitted for rodenticide baits are certain approved dye substitutions.)

Since the Rodenticide Cluster RED was issued, SRRD has convened Stakeholder meetings and assorted other meetings to discuss the requirements stated in the RED. It now appears that SRRD is likely to abandon the requirement to add the indicator dye and probably that for the bittering agent as well.

If adding a bittering agent to this bait would reduce the extent of exposures of children to it without adversely affecting the effectiveness of the product in controlling house mice, the formulation change would be a good thing, considering the history of evident misuse of d-Con baits (which dominate the over-the-counter rodenticide market in the U.S.). A bittering agent would not be expected to reduce the number of child exposure incidents that occur but might reduce the amounts of bait taken in. Bittering agents probably would not deter feeding on baits by infants. The most popular bittering agent (Bitrex) for adulterating baits would not be expected reduce the occurrence or extent of exposures of dogs and other nontarget animals to rodenticide baits. If 3282-81 were only used according to the <u>wording</u> on the labeling that we have accepted for it, there would be no need for a bittering agent in the formulation because primary nontarget exposures would be virtually precluded.

201.0 DATA SUMMARY

This product initially was registered without supporting efficacy data. Submission of efficacy data "within 15 months" of the date of registration was one of the

conditions of registration. Efficacy data relevant to the current composition of 3282-81 (see CSF of 12/5/88) were discussed in the efficacy reviews of 5/14/90 and 7/16/90. In the latter review, I accepted rat and mouse efficacy data for 3282-66. In that same review, I rejected the rat efficacy data submitted for 3282-81 because the bait was poorly accepted by most subjects and composite bait acceptance scores for the replicates were 28.1% and 18.1%, well below the 33% criterion. There also were 3 survivors (all males) among the 40 rats exposed to the toxic bait in these choice-test replicates.

The efficacy review of 10/15/90 discussed results of two additional replicates of rat efficacy trials with what was claimed to be the 3282-81 product. In those trials, composite bait acceptance scores were 40.3% and 45.0%, with all bait-exposed animals dying. However, there were 3 extremely marginal feeders (<5% acceptance). As the identity of the test material to the current composition of 3282-81 was not clearly established, the efficacy data discussed in the efficacy review were not accepted. To this day, it appears that the registrant has failed to establish this link and, therefore, that the rat claims made for 3282-81 technically still are not supported.

The relatively poor acceptance of 3282-81 may have been due to the fact that it consists of crumbled 3282-74 pellets (see efficacy review of 1/18/89). 3282-81 was created as a Brodifacoum-containing counterpart to d-Con's "READY MIXED" Warfarin-containing bait, 3282-4, when the d-Con Company replaced its Warfarin line with Brodifacoum baits. An important difference between the two products is that the well-accepted 3282-4 (still registered) is largely a mixture of grains while 3282-81 consists of crumbled pellets which would be expected to be inefficient for rats to eat and not particularly attractive to them.

For reregistration, new efficacy data definitely will have to be generated for 3282-81 product if d-Con wishes to retain any sort of single-feeding claim for these products. If any of the Phase I reformulation requirements (indicator dye and bittering agent) from the Rodenticide Cluster Reregistration Eligibility Decision (RED), which pertains to Brodifacoum and 5 other compounds, remain in force following the ongoing "Stakeholder" meetings, this product will have to be reformulated and tested for efficacy. Currently, this product contains a dye but no bittering agent.

The CSF of 10/6/99 differs from that of 12/5/88 in many ways. Bitrex is not mentioned on the CSF of 10/6/99, but would be included by switching the source product for

Inert ingredient information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

Brodifacoum from [redacted]. Other differences between the CSFs of 12/5/88 and 10/6/99 include [redacted]

To make a bait that is nominally 0.005% Brodifacoum, the [redacted] if the CSF of 10/6/99 were accepted.

The efficacy reports submitted on 10/12/99 are cited and discussed individually below.

Mach, J.J. (1999a) Standard Norway rat (*Rattus norvegicus*) anticoagulant placepack dry bait laboratory test method with d-Con Bait Pellets II Kills Rats and Mice or d-Con LIM-N8 Rat Killer. Unpublished report, Study No. 98047, Genesis Laboratories, Inc., Wellington, CO. 47 pp.

MRID# 449496-03

This study was completed on 3/15/99, well after the RED was to be mailed to registrants. The bioassay itself was begun in January of 1999. The study was a placepack-penetration test. Such a study is not needed for 3282-81, which is a bait-tray product.

The test substance used in this study is described as "a rodenticide bait containing 50 ppm brodifacoum" and as

> "light blue-green pellets in a cellulose packaging approximately 3 x 5 inches in dimension with an average weight of 34.6 ± 0.6 grams."

3282-81 is supposed to consist of crumbled pellets rather than intact pellets. Therefore, this study seems to be irrelevant to 3282-81.

Following receipt by the test facility, the bait was "placed in a walk-in freezer." The relevant protocol (1.217) for this type of study makes no mention of storage conditions for the test material. The assumption (and practice when we had a test facility) is that the bait is to be stored at room temperature to simulate conditions during the, shipping, marketing,and pre-use storage phases of product life. I do not know to what extent freezing and thawing might alter the palatability of a bait such as 3282-74 (the pelleted bait in placepacks that may have been used in this study).

There is no batch number indicated in the efficacy report itself. A report of chemical analysis appended to the efficacy report appears to claim the test material -- "98-TS-43" -- to have been 0.00547% ($\pm$0.00015) Brodifacoum. Reportedly, no Brodifacoum was found in the challenge diet (LoD = 0.000053%, LoQ = 0.000188%). The sample number probably was assigned by the test facility.

Study subjects were selected from a pool of "Sixty-six Norway rats (32 female, 32 male)" of the Wistar laboratory strain. The rats were obtained from Harlan Sprague Dawley. The rats reportedly were

> housed in pens in groups of 10 plus an extra animal in pens A, B, C, and D for assurance only healthy rats were used for the exposure test. The pens had a solid concrete bottom and aluminum metal wall that had a floor surface area of 18,347 cm^2.

That area is equivalent to that of a 4.44-ft square. The "extra animal" approach certainly is not called for in Protocol 1.217.

The animals were maintained on laboratory chow for 7 days prior to the start of the test. Rats were assigned to one of two test groups or to the control group. At the start of the acclimation period, each test group consisted of 10-11 males and 10-11 females (i.e., one single-sex subgroup for each gender). According to Mach,

> At the end of acclimation, 1 rat was arbitrarily removed from the pens with 11 animals so 10 healthy rats remained in each of the pens for the exposure test.

While it is preferred to start bait-exposure periods with 10 healthy animals per subgroup (see below), culling an animal from a social group right before that period begins would be a disruptive procedure. If animals become unhealthy during the acclimation period, there might be other factors working in concert with the toxicant to cause mortality once the bait-exposure period begins.

For the bait exposure and follow-up periods, 3 food containers ("identical metal cups") were positioned "on opposite sides of the pen"(?). The food containers were used to provide

> A total of approximately 90 grams of challenge diet was presented in each treatment and control pen at the beginning of the test. On Day 1 of the exposure test, more challenge diet was added to the cups because the rats appeared to be eating the entire amount. The cups were almost filled throughout the remainder of the study.

The most recent ("9-3-92") version of Protocol 1.217 permits "single-sex subgroups of 5 or 10 animals" and indicates that challenge diet "should be available in each cage at all times". The traditional rule-of-thumb for consumption/wasting of bait by a Norway rat is "an ounce of grain a day". By that index, more than 283 g of bait should have been placed in a pen occupied by 10 rats to ensure that challenge diet was present "at all times". Mach's account suggests that rats depleted most of the challenge diet (about 30% of the minimum that should have been placed) early on the first day of the bait exposure period. Such depletion may have increased interest in placepacks. In my opinion, the failure to provide enough challenge diet at the onset of the bait-exposure phase renders this study worthless as an efficacy trial.

Mach reports that "15 individual placepacks" were deployed in each test-group pen at the start of the bait-exposure period. This means that there was about 5 times as much bait as challenge diet available to rats at the start of the actual test.

The bait exposure period was to have been maintained for 15 days (as Protocol 1.217), but all test-group rats were dead after 12 days. Control-group animals were maintained on challenge diet for 17 days (1/4-1/21/99), which represented a 12-day test phase and a 5-day follow-up. Mach issued a "**PROTOCOL AMENDMENT**" on 2/18/99 to cover this change in procedure, which occurred on or about 1/16/99. At paragraph 8.1, Protocol 1.217 requires that the control

group be maintained for the full scheduled 15-day baiting period plus the 5-day follow-up period.

Mach reports that all 20 bait-exposed males died and that all 20 bait-exposed females also died. The mortality scores of 100% for both replicates exceeded the criterion of 90% mortality for Protocol 1.217. According to the report, signs of premorbid toxicity reportedly were observed in at least some of these victims. The females died 3-12 days after the onset of bait exposure, while the males died in 4-10 days. All control-group animals reportedly survived and showed no "signs of intoxication".

At the "Initiation of Exposure" males were heavier than females. At that time, females averaged 229 g in the control group and 227 g and 229 g in the two test groups. Males averaged 259 g in the control group and 259 g in each of the two test groups.

Fourteen of 16 test-group females for which weight at death was determined lost weight after the onset of the bait-exposure period. Two females gained (3 and 6 g). Final weights were not determined for two females for each test group because

> The female rats numbered 4 and 5 of Pen F were mixed up with two females from Pen B.

Over the same period of time, all 10 control-group females gained weight (16-67 g).

Nineteen of 20 test-group males lost weight after the start of the bait-exposure period. One test-group male gained 7 g. All 10 control group males gained weight (42-82 g).

Mach's "Table III" indicates that 62 and 68 placepacks were deployed in the two test subgroups comprised by males, with 53 reported to have been "Consumed" by each male subgroup and the other 9 and 15 packs "Remaining". For one female subgroup, the numbers were 65 packs deployed, 50 "Consumed", and 15 "Remaining". For the other female subgroup, the numbers were 90 packs deployed, 77 "Consumed", and 13 "Remaining".

The test environment reportedly ranged wildly in temperature, the mean daily maximum and minimum temperatures being $20\pm1^{\circ}C$ and $14\pm1^{\circ}C$, respectively, in the acclimation period; and $19\pm1^{\circ}C$ and $14\pm1^{\circ}C$, respectively, over the bait-exposure and follow-up periods. Actual temperatures reported ranged from $13^{\circ}C$ to $21^{\circ}C$ ($55.4-69.8^{\circ}F$) during the acclimation period and $12^{\circ}C$ to $21^{\circ}C$ ($53.6-69.8^{\circ}F$) during the bait-exposure and follow-up

periods. The relevant EPA protocol (1.217) requires temperatures to be between 20°C and 25°C (68-77°F).

Mean maximum and minimum daily relative humidities were 33±3% and 28±3%, respectively, during the acclimation period. Mean maximum and minimum daily relative humidities were 32±5% and 26±2%, respectively, during the bait-exposure and follow-up periods. These means were below the required range of 50-55%. Actual relative humidities ranged from 24% to 37% during the acclimation period and 24% to 45% during the bait-exposure and follow-up periods. These figures and the temperature data suggest that temperature and humidity were not well controlled in the test room and that outdoor ambient conditions greatly affected indoor conditions.

This study is not acceptable because of the failure to provide an adequate amount of challenge diet at the onset of the bait-exposure period. The description of test material as a pelleted bait in a placepack would seem to make the study irrelevant in any case to 3282-81, which is supposed to consist of pulverized bait (formerly pelletized) in bait trays. Other problems with this study include the failure to report raw data, failure to control the test environment (which was always too dry and usually too cold), and procedural irregularities involving the handling of animals. The test material should not have been frozen prior to use because people who retail and buy rat-and-mouse baits are neither instructed nor expected to freeze baits until it is time to use them.

The relevance of this study to the proposed new formulation is not established by Mach's report, which does not mention Bitrex and does not identify a batch number for the test material. The batch number mentioned in the report of analysis is not mentioned in the report for the bioassay and, in any case, probably was assigned by Genesis rather than the formulator.

Mach, J.J. (1999b) Standard house mouse (*Mus musculus*) anticoagulant placepack dry bait laboratory test using d-Con Bait Pellets II Kills Rats and Mice or d-Con Bait Pellets II Kills Mice. Unpublished report, Study No. 98046, Genesis Laboratories, Inc., Wellington, CO. 46 pp.

MRID# 449496-02

This study was completed on 3/15/99, well after the RED was to be mailed to registrants. The bioassay itself was begun in December of 1998. The study was a placepack-penetration

test. Such as study is not needed for 3282-81, which is a bait-tray product.

The test substance used in this study is described as "a rodenticide bait containing 50 ppm brodifacoum" and as

> "light blue-green pellets in a cellulose packaging approximately 3 x 5 inches in dimension with an average weight of 34.6 ± 0.6 grams."

3282-81 is supposed to consist of crumbled pellets rather than intact pellets. Therefore, this study seems to be irrelevant to 3282-81.

Following receipt by the test facility, the bait was "placed in a walk-in freezer." The relevant protocol (1.218) for this type of study makes no mention of storage conditions for the test material. The assumption (and practice when we had a test facility) is that the bait is to be stored at room temperature to simulate conditions during the, shipping, marketing,and pre-use storage phases of product life. I do not know to what extent freezing and thawing might alter the palatability of a bait such as 3282-74 (the pelleted bait in placepacks that probably was used in this study).

There is no batch number indicated in the efficacy report itself. A report of chemical analysis appended to the efficacy report appears to claim the test material -- "98-TS-43" -- to have been 0.00547% (±0.00015) Brodifacoum. Reportedly, no Brodifacoum was found in the challenge diet (LoD = 0.000053%, LoQ = 0.000188%). The sample number probably was assigned by the test facility.

Study subjects were selected from a pool of 63 adult Swiss-Webster strain laboratory house mice obtained from a commercial source. Mice reportedly were

> housed in pens in groups of 10 plus an extra animal during the acclimation period in pens B, C, and F. For assurance only healthy mice were used for the exposure test. The pens had a solid metal bottoms and metal walls and had a floor surface area of 6813 cm^2.

That area is equivalent to that of a 2.7-ft square. The "extra animal" approach certainly is not called for in Protocol 1.218.

The animals were maintained on laboratory chow for 7 days prior to the start of the test. Mice were assigned to one of two test groups or to the control group. At the start

of the acclimation period, each test group consisted of 10-11 males and 10-11 females (i.e., one single-sex subgroup for each gender). According to Mach,

> Two male mice from pen D died on days 6 and 7 of the acclimation period. On the same day as they died, the dead mice were replaced by healthy mice from pens B and F. No diseases were observed and no medication was provided to any of the mice. A single female mouse was arbitrarily removed from pen C so only 10 mice were in all of the treatment groups.

While it is preferred to start bait-exposure periods with 10 healthy animals per subgroup (see below), culling an animal from a social group right before that period begins would be a disruptive procedure. Even more disruptive would be adding one of such culled animals to each of two male subgroups. If animals become unhealthy during the acclimation period, there might be other factors working in concert with the toxicant to cause mortality once the bait-exposure period begins.

At the start of the acclimation period and throughout the study, mean weights of male and female subgroup animals were equal within each group. In the control group, male and female subgroups both averaged 20.5 g. In one of the test groups, male and female subgroups also both averaged 20.5 g. In the second test group, male and female subgroups both averaged 21.0 g.

For the test, each pen was equipped with two food containers ("identical metal cups") deployed "on opposite sides of the pen." These cups were loaded with a total of 80 g of EPA rat-and-mouse challenge diet. (Mach reports that "a rat challenge diet was used for this test". My current copies of Protocols 1.217 and 1.218 describe the same challenge diet composition and particle sizes for rats and mice.) Six place packs containing the test bait were also offered. The bait exposure period lasted 13 of a scheduled 15 days. Mach shortened the bait-exposure period because all test-group mice died within 13 days of its onset and moved the control group animals to the 5-day follow-up period. Protocol 1.218 (paragraph 8.1) states that the test is not to be shortened

> even if all mice exposed to the toxic bait die in less than 15 days.

Mach reports that all 20 bait-exposed males died and that all 20 bait-exposed females also died. The mortality scores of 100% for both replicates exceeded the criterion

of 90% mortality for Protocol 1.218. According to the report, signs of premorbid toxicity reportedly were observed in at least some of the apparent victims. The females died 4-13 days after the onset of bait exposure, while the males died in 4-10 days. All control-group animals reportedly survived, showing no "signs of intoxication or sickness".

Nineteen of 20 test-group females lost weight after the onset of the bait-exposure period. One female victim gained 0.5 g (the limit of precision of the weighing effort). Over the same period of time, 3 of 10 control-group females lost weight (1.0-3.5 g, despite showing no signs of sickness), while 6 gained (0.5-3.0 g) and one maintained. Nineteen of 20 test-group males lost weight after the start of the bait-exposure period, with the other male maintaining his weight despite dying. Two of 10 control group males lost weight (1.5 g and 4.5 g), while 7 gained (0.5-6.0 g) and one maintained. Loss of weight in control-group animals usually is rare in laboratory efficacy studies.

Mach's "Table III" indicates that 10 and 12 placepacks were deployed in the two test subgroups comprised by males, with 4 and 6, respectively, reported to have been "Consumed" by each subgroup and the other 6 packs per subgroup "Remaining". For one female subgroup, the numbers were 22 packs deployed, 16 "Consumed", and 6 "Remaining". For the other female subgroup, the numbers were 29 packs deployed, 24 "Consumed", and 5 "Remaining".

The test environment reportedly ranged wildly in temperature, the mean daily maximum and minimum temperatures being $20\pm1^{\circ}C$ and $15\pm1^{\circ}C$, respectively, in the acclimation period; and $21\pm1^{\circ}C$ and $15\pm3^{\circ}C$, respectively, over the bait-exposure and follow-up periods. Actual temperatures reported ranged from $14^{\circ}C$ to $21^{\circ}C$ ($57.2-69.8^{\circ}F$) during the acclimation period and $10^{\circ}C$ to $22^{\circ}C$ ($50-71.6^{\circ}F$) during the bait-exposure and follow-up periods. The relevant EPA protocol (1.218) requires temperatures to be between $20^{\circ}C$ and $25^{\circ}C$ ($68-77^{\circ}F$).

Mean maximum and minimum daily relative humidities were $29\pm2\%$ and $23\pm1\%$, respectively, during the acclimation period. Mean maximum and minimum daily relative humidities were $27\pm5\%$ and $22\pm3\%$, respectively, during the bait-exposure and follow-up periods. These means were well below the required range of 50-55%. Actual relative humidities ranged from 22% to 33% during the acclimation period and 15-41% during the bait-exposure and follow-up periods.

Based on the information provided, I will not accept this study at this time. There is no reporting of raw data. The test environment was not well controlled and the shifting of animals from pen to pen is an irregular procedure. This study may be salvageable if the raw data are provided, but the study does not seem to be relevant to 3282-81 because a different product and bait form was used.

The relevance of this study to the proposed new formulation is not established by Mach's report because it does not mention Bitrex and does not identify a batch number for the test material. The batch number mentioned in the report of analysis is not mentioned in the report for the bioassay and probably was generated by Genesis rather than the formulator.

202.0 CONCLUSIONS

1. Except for a limited range of approved dye substitutions, we do not permit alternate formulations for rodenticide baits. We do not permit "with Bitrex" and "without Bitrex" formulations under a single registration number. Comparing your proposed revised Confidential Statement of Formula (CSF) of October 6, 1999, with the current CSF of record for 3282-81 reveals that wholesale modifications to the formulation are proposed which are unrelated to the proposed addition of Bitrex. You must either replace the current formulation of 3282-81 with the new Bitrex-containing formulation or you must apply for a new registration for the Bitrex-containing formulation.

2. The rat placepack-penetration study (MRID No. 449496-03) is not acceptable because of the testing facility's failure to provide an adequate amount of challenge diet at the onset of the bait-exposure period. This deficiency biased the test in favor of the product as about 5 times as much bait as challenge diet was available to rats at the beginning of the test.

   The description of test material as a pelleted bait in a placepack would seem to make the study irrelevant in any case to 3282-81, which is supposed to consist of pulverized bait (formerly pelletized) in bait trays. Other problems with this study include the failure to report raw data, failure to control the test environment (which was always too dry and usually too cold), and procedural irregularities involving the handling of animals. The test material should not have been frozen prior to use because people who retail and buy rat-and-mouse baits are neither instructed nor expected to freeze baits until it is time to use them.

The relevance of this study to the proposed new formulation is not established in the bioassay report, which does not mention Bitrex and does not identify a batch number for the test material. A batch number mentioned in the report of analysis is not mentioned in the report for the bioassay and probably was assigned by the testing facility rather than the formulator.

3. The mouse placepack-penetration study (MRID No. 449496-03) is not acceptable at this time. Problems with this study include the failure to report raw data, failure to control the test environment (which was always too dry and usually too cold), and procedural irregularities involving the handling of animals. The test material should not have been frozen prior to use because people who retail and buy rat-and-mouse baits are neither instructed nor expected to freeze baits until it is time to use them. If raw data are provided, we will reconsider this study.

   The description of test material as a pelleted bait in a placepack would seem to make the study irrelevant in any case to 3282-81, which is supposed to consist of pulverized bait (formerly pelletized) in bait trays.

   The relevance of this study to the proposed new formulation for 3282-81 (or any of your other products) is not established in the bioassay report, which does not mention Bitrex and does not identify a batch number for the test material. The batch number mentioned in the report of analysis is not mentioned in the report for the bioassay and probably was assigned by the testing facility rather than the formulator. Without appropriate documentation, we cannot be sure to what formulation this study applies.

[NOTE TO DAN PEACOCK: Even with a 75-day extension given almost 2 months after the expiration of the 30 days originally given by our letter of 7/1/99, revised labeling for this product is overdue once again.]

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
January 7, 2000

Bill

DP BARCODE: D261162

CASE: 027444 DATA PACKAGE RECORD DATE: 11/17/99
SUBMISSION: S571293 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE
RANKING : 10 POINTS ()
CHEMICALS: 112701 Brodifacoum (ANSI) 00.0050%

ID#: 003282-00081 D-CON READY MIXED GENERATION II
COMPANY: 003282 RECKITT & COLMAN INC, HOUSEHOLD PRODUCTS DIVISION
PRODUCT MANAGER: 04 TINA LEVINE 703-308-7055 ROOM: CM2 219
PM TEAM REVIEWER: DANIEL PEACOCK 703-305-5407 ROOM: CM2 221
RECEIVED DATE: 10/14/99 DUE OUT DATE: 04/21/00

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 261162 EXPEDITE: N DATE SENT: 11/17/99 DATE RET.: / /
CHEMICAL: 112701 Brodifacoum (ANSI)
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 04/15/00
DIV : RD	/ /	/ /	NEGOT DATE: / /
BRAN: IRB	/ /	/ /	PROJ DATE: / /
SECT: PM04	/ /	/ /	
REVR : [illegible]	12/8/99	1/7/00 OBJ	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Bill,

please review alternate formula, including data.
1 of 4 products
Dan

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DATE OUT: 12/FEB/2000

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:Manufacturing-Use [ ] End-Use Product [X]
DP BARCODE No.D261163 **RECEIVED DATE:**14/OCT/1999 **REG./File Symbol No.:**3282-81
PRODUCT: D-Con Ready Mixed Generation II, 0.005% Brodifacoum **MRID** 449496-01
COMPANY NAME: Reckitt & Colman, Inc. Household Products Division **Action Code:**305

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 04 Tina Levine/Daniel Peacock
Insecticide-Rodenticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 12/OCT/1999, the applicant requested review for acceptability an alternate formulation, CSF dated 06/OCT/1999. In support of this action, the applicant included some product chemistry data pertaining to the physical/chemical properties and the current label, approved on 28/JAN/1999, and a basic formulation, CSF dated 14/JUN/1991.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 11/JAN/1999 was included with this submission claiming no confidentiality of any of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C).

2. A GLP statement dated 11/JAN/1999 was included with this submission to the effect that the submitted studies were conducted in compliance with GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #449496-01 The submitted study entitled: "Bait Pellets End-Use Product: Determination of Color, Physical State, Odor, Density, Specific Gravity, and pH", was authored by Ronald J. Harkrader, Ph.D.& Valerie L. Fuhrman; Performed by Genesis Laboratories, Inc. of Wellington, Colorado; Completed on 15/JAN/1999 (24 pages).

GRN 830-6302 Color: Green-Blue

GRN 830-6303 Physical State: Granular solid.

GRN 830-6304 Odor: Grain-very slight

GRN 830-7300 Density: 0.712 g/ml

Product ingredient source information may be entitled to confidential treatment

GRN 830-7000 pH: 6.61

FINDINGS:

1. The subject product is produced by a non-integrated formulation system meaning that the technical source, brodifacoum, is registered, Reg. No. [redacted]

2. The subject product is substantially similar to the current basic formulation, CSF dated 14/JUN/1991, except for using an alternate source of brodifacoum, Reg. No. [redacted] instead of the current Reg. No. [redacted] No change in the physical/chemical properties in the submitted alternate formulation relative to the current basic formulation.

3. The submitted product's alternate formulation CSF dated 06/OCT/1999 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations.

CONCLUSIONS:

We have no objections for approval of the submitted alternate formulation, CSF dated 06/OCT/1999.

cc:S. Malak and Central File (Reg. No. 3282-81).
7505C:RD:TRB:CM-2:Rm.268:s.m.:12/APR/2000:703-308-9365:<3282-81>.

Clen
#10338

DP BARCODE: D261163

CASE: 027444 DATA PACKAGE RECORD DATE: 11/17/99
SUBMISSION: S571293 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE
RANKING : 10 POINTS ()
CHEMICALS: 112701 Brodifacoum (ANSI) 00.0050%

ID#: 003282-00081 D-CON READY MIXED GENERATION II
COMPANY: 003282 RECKITT & COLMAN INC, HOUSEHOLD PRODUCTS DIVISION
PRODUCT MANAGER: 04 TINA LEVINE 703-308-7055 ROOM: CM2 219
PM TEAM REVIEWER: DANIEL PEACOCK 703-305-5407 ROOM: CM2 221
RECEIVED DATE: 10/14/99 DUE OUT DATE: 04/21/00

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 261163 EXPEDITE: N DATE SENT: 11/17/99 DATE RET.: / /
CHEMICAL: 112701 Brodifacoum (ANSI)
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: TRB	/ /	/ /
SECT: CHEM	/ /	/ /
REVR : S. Malek	3/30/00	4/12/00
CONTR:	/ /	/ /

ADMIN DUE DATE: 3-6-00 ~~04/15/00~~
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

chemist,

please review chemistry data for alternate formula.

Dan

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
261162	IRB/PM04	11/17/99	04/15/00	Y	Y	Y

FEB 16 2000

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

306 5-576327

RECKITT & COLMAN INC.
HOUSEHOLD PRODUCTS DIVISION
1800 VALLEY ROAD
WAYNE, NJ 07474

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 02/10/00. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

RECKITT & COLMAN

450377-00

February 8, 2000

Document Processing Desk (Suppl)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
Room 223, Crystal Mall 2
1021 Jefferson-Davis Highway
Arlington, Virginia 22202-4501
Attn: Dan Peacock PM-14

RE: d-Con Ready Mix Generation II
EPA Registration Number 3282-81
OPP Identifier Number 252954
Supplemental Information on 1 Year Storage and Stability

Dear Mr. Peacock:

Reckitt & Colman Inc. is submitting additional information to support the alternate formulation containing Bitrex. In support of this registration action the following information is being submitted:

1) Bait Pellets End-Use Product Determination of Storage and Stability and Corrosion Characteristics.
45037701 Study Number 98040

If there is any other information that is needed to complete this amendment, please feel free to contact me at **973-686-7390**. I thank you for taking care of this registration submission.

Sincerely:

Sean McNear

Sean McNear
Sr. Regulatory Affairs Specialist

RECKITT & COLMAN

449496-00

October 12, 1999

Document Processing Desk (AMEND)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
Room 223, Crystal Mall 2
1921 Jefferson-Davis Highway
Arlington, Virginia 22202-4501
Attn: Dan Peacock PM-14

RE: D-Con Ready Mix Generation II
EPA Registration Number 3282-81
Amendment for alternate formulation containing Bitrex

Dear Mr. Peacock:

Reckitt & Colman Inc. is submitting an alternate formulation amendment for the above registration to incorporate the ingredient Bitrex to our D-Con Ready Mix Generation II product. In support of this registration action the following information is being submitted:

1) EPA Pesticide Registration Form 8570-1, OPP Identification Number 252954.

2) Confidential Statement of Formula Form 8570-4 dated October 6, 1999.

3) Product Chemistry Series 63: Physical and Chemical Characteristics 63-2, 63-3, 63-4, 63-7, and 63-12 study number 98041.

4) Efficacy study for House Mouse, Guideline 96-10 Commensal Rodenticides, study number 98046.

5) Efficacy study for Norway Rat, Guideline 96-10 Commensal Rodenticides, study number 98047.

If there is any other information that is needed to complete this amendment, please feel free to contact me at **973-686-7390**. I thank you for taking care of this registration submission.

Sincerely:

Sean McNear

Sean McNear
Sr. Regulatory Affairs Specialist

Product Name: **D-Con Ready Mix Generation II**

EPA File Symbol 3282-81

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Reckitt & Colman, Inc.
1655 Valley Road
Wayne, NJ 07645

2. Regulatory action in support of which this package is submitted:

AMENDMENT

3. Transmittal date:

October 11, 1999

4. Vol. 1 Administrative materials

A) Cover letter
B) Application
C) Confidential statement of formula

5. Vol. 2 Product Chemistry 44949601

Subdivision D: Product Chemistry, Series 63; Physical and Chemical Characteristics 63-2, 63-3, 63-4, 63-7, and 63-12
Study Title: Bait Pellets End-Use Product: Determination of Color, Physical State, Odor, Density/Specific Gravity, and pH
Study Number: 98041

Vol. 3 Efficacy 44949602

Standard House Mouse (*Mus musculus*) Anticoagulant Placepack Dry Bait Laboratory Test Method with d-Con Bait Pellets II Kills Rats and Mice or d-Con Bait Pellets II Kills Mice
Study Number: 98046

7. Vol. 4 Efficacy 44949603

A) Standard Norway Rat (*Rattus norvegicus*) Anticoagulant Placepack Dry Bait Laboratory Test Method with d-Con Baits Pellets II Kills Rats and Mice or d-Con LIM-N8 Rat Killer
Study Number: 98047

Company Official: Sean McNear Sean McNear

Company Name: Reckitt & Colman Inc.

Company Contact: Sean McNear (973) 686-7390

AMENDMENT

APPLICATION FOR AMENDMENT

N/FT

WITH DATA	INIT.	DATE
FEU	~~fw~~	~~10-20-99~~
SIG (DATA)		
PM	~~04~~	
OPP #	~~252954~~	

WITHOUT DATA	INIT.	DATE
FEU		
PM		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
October 20, 1999

RECKITT & COLMAN INC.
1655 VALLEY ROAD
WAYNE, NJ 07474

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ATT: SEAN MCNEAR

PRODUCT NAME: D-CON READY MIX GENERATION II
OPP IDENTIFICATION NUMBER: 252954
EPA REGISTRATION NUMBER: 3282-81
EPA RECEIPT DATE: 10/15/99

SUBJECT: RECEIPT OF AMENDMENT

Dear Registrant:

The Office of Pesticide Programs has received your application for an amendment.

The package will now be forwarded to the Product Manager for review to determine its acceptability.

Please note that this is only a notification of receipt and does not constitute approval of your application.

If you have any questions, please contact Dan Peacock, Product Manager 04, at 703-305-5404.

Sincerely,

J. Price

Front End Processing Staff
Information Services Branch
INFORMATION RESOURCES & SERVICES DIVISION

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number: 252954

Application for Pesticide - Section I

1. Company/Product Number: D-Con Ready Mix Generation II

2. EPA Product Manager: Dan Peacock
PM#: PM-04

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): 3282-81

5. Name and Address of Applicant *(Include ZIP Code)*
Reckitt & Colman Inc.
1655 Valley Road
Wayne, New Jersey 07474
[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment for an alternate formulation to add Bitrex

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [X] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container

5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [X] Other Printed on Container

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Sean McNear	Sr. Regulatory Affairs Specialist	973-686-7391

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Sean McNear	Sr. Regulatory Affairs Specialist	
4. Typed Name: Sean McNear	5. Date: October 11,1999	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must heve en authorized agent residing in the United States to ect for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrati[illegible] that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

5 569002

CERTIFIED MAIL

Ms. Patricia Sheehy
Reckitt & Colman, Inc.
1655 Valley Road
P.O. Box 943
Wayne, NJ 07474-0943

SEP 28

Subject: Request for Time Extension
d-Con Mouse Prufe II
EPA Registration No. 3282-65
d-Con Bait Pellets II
EPA Registration No. 3282-74
d-Con Ready Mixed Baitbits
EPA Registration No. 3282-81
Our letter of July 1, 1999

Dear Ms. Sheehy:

In our letter dated July 1, 1999, we requested you modify your labels and submit revisions within 30 days of receipt of that letter. In a phone conversation with Grace M. Robiou on September 24, 1999, you requested an extension to our request.

If the above requested information, or a written request for additional time is not submitted to the Registration Division within 75 days of the date of the receipt of this notice, these registrations will be subject to cancellation in accordance with FIFRA sec. 6(e).

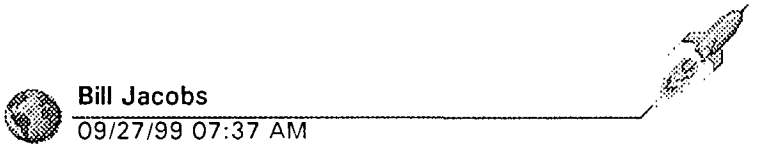
Should you have any questions about this letter, you may reach Grace M. Robiou at 703-305-1016.

Sincerely,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7505C)

F:\USER\GROBIOU\CORRESPONDENCE\Bromadiolone\~~3282-65(2).wpd~~
3282-81(2).wpd

3282's



Bill Jacobs
09/27/99 07:37 AM

To: Grace Robiou/DC/USEPA/US@EPA
cc:
Subject: Extension to Reckitt-Coleman

My notebook indicates that on 7/14/99, you forwarded a phone message from Patricia Sheehy to me regarding the using up of old labels for 3282-65, 3282-74, and 3282-81 in channels of trade. I have no notes indicating that I ever talked to Ms. Sheehy, and it may have been that you forwarded the message to me just to ask me what we might do about it. I have no notes about granting d-Con an extension and doubt that one would have been granted verbally. It seems that if she was calling us on 7/14/99 (or earlier) concerning labels for the products affected by our letters of 7/1/99, she would have known about the letters before August. You might want to ask Tina and Rita, if Dan has no notes or recollection of granting an extension for the d-Con products.

---------- Forwarded by Bill Jacobs/DC/USEPA/US on 09/27/99 07:21 AM ----------

Grace Robiou 09/24/99 12:41 PM

To: Dan Peacock/DC/USEPA/US@EPA, Bill Jacobs/DC/USEPA/US@EPA
cc:
Subject: Extension to Reckitt-Coleman

Dan, Bill,

Spoke with new person there (Patricia Sheehy). Our 7/1/99 letter with the 30-day cancellation notice didn't get to her until August. She said she or someone else called and someone here authorized her an extension until late October. Did either or you talk to her about this? I will write a letter with such an extension, regardless.

Thanks,
Grace

5-559909

JUL 1 1999

CERTIFIED MAIL

Mr. Bob Fellows
Reckitt & Colman, Inc.
1655 Valley Road
P.O. Box 943
Wayne, NJ 07474-0943

Subject: General Label Update
d-Con Ready Mixed Baitbits
EPA Registration No. 3282-81
Your letter dated March 10, 1999

Dear Mr. Fellows:

In your submission of March 10, 1999, you provided us with draft labeling revised to reflect "all required label language consistent with current regulations". We find that your recent submission does not incorporate changes already made to your last stamped label, dated January 28, 1999. For your submission to be considered, you must modify the proposed labeling as indicated below, and submit revisions within 30 days of receipt of this letter. This registration will be subject to cancellation in accordance with FIFRA sec. 6(e) if you do not comply with these conditions.

Revisions to 12-oz and 3-lb Boxes

1. The registrant's name, the product's registration number, and the establishment number must appear on the label for the 3-lb box as well as on the label for the 12-oz box.

2. Be aware that no graphics have been proposed for inclusion on the box labels. Therefore, no graphics may appear on them. We previously have forbidden the use of unreviewed graphics for this product via our letters of February 1, 1996, and December 4, 1998. In your letter of January 8, 1999, you erroneously characterized this prohibition as a "recommendation" and asserted that

> "The graphics on the product label demonstrate the appropriate placement of the product and proper use of tamper resistant bait stations.

We disagree with that characterization. One of the graphics used on labels of d-Con rat baits shows a bait tray being placed into a bait station, while another shows a bait station being locked. However, there is no evidence of baffling or bait-containment structures within the bait station. The entrances to the bait station being loaded appear to be very close to the likely destination of the bait tray -- close enough for a small child to reach through the rodent entry ports and get to the bait tray. Consequently, the bait station depicted in those graphics falls far short of being tamper-resistant, whether or not it is locked and secured. See PR Notice 94-7 for a list of criteria for tamper-resistant bait stations.

Other graphics traditionally used on printed labels for 3282-81 show a bait station under a storage shelf in what appears to be a wooden-walled structure, a "lean board" positioned against an indoor wall of a similar structure, a person opening a bait tray using a bare hand, and, on the front panel, a Norway rat feeding from an opened bait tray that appears to have been placed out in the open.

We have no objections to graphics that illustrate appropriate product use. Considering the use and incident history of rodenticide baits, we must review such graphics before they may be added to product labeling. Graphics are not to detract from the required bait-protection text which appears on the label.

3. "**FRONT LABEL**"

i. Delete the claim "Flavor attractive to mice and rats". This claim may be false and is certainly misleading as all registered anticoagulant baits must pass tests similar to those required for this bait, which neither rats nor mice accepted as well as they did our challenge diet.

A bait acceptance problem with this product was discovered when we reviewed rat efficacy data submitted (MRID Nos. 413082-01 and 415247-01) for 3282-81 in 1990. Data (MRID No. 416037-01) submitted subsequently in that year suggested better bait acceptance by rats, but the test bait was not sufficiently linked to this product's formulation. Therefore, the claims made for this bait are not supported by data which demonstrate adequate bait acceptance by rats. See our letters of October 30, 1990, and February 1, 1996, for more discussion of this point.

ii Delete the claim "CAN KILL IN ONE FEEDING" and the asterisk which precedes the sentence "Rats and mice may ... begins." You must delete this claim altogether from your label, taking care not to

move it to a different label panel. We have concluded that the only solution to this problem is to ban use of the "CAN KILL IN ONE FEEDING" portion of the claim entirely. By themselves, those words comprise

> A true statement used in such a way as to give a false or misleading impression to the purchaser.

Such statements are prohibited under 40 CFR, §156.10(a)(5)(vii).

The "CAN KILL IN ONE FEEDING" claim is misleading. Although a single day's feeding might load a rat or mouse with enough poison to cause its death, that death is not going to occur for several more days, during some of which time the lethally dosed rodents will feed relatively normally. An ordinary person who reads "CAN KILL IN ONE FEEDING" is likely to expect to see dead rodents in one day and may use less bait than is needed to control the infestation.

4. "**BACK LABEL**"

i. The proposed change to the "**To Control House Mice:**" portion of the "**APPLICATION DIRECTIONS:**" subsection of the "**DIRECTIONS FOR USE**" is not acceptable. The new text implies open-air placements "indoors and against the outside walls of buildings", and all such placements would grossly exceed the amount of bait needed to control house mice. The proposed new directions might encourage nontarget exposures of young children, pets, and nontarget wildlife to Brodifacoum bait.

The "**To Control House Mice:**" text must continue to read as shown immediately below.

> **To Control House Mice:** Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

ii Change "contained" to "container" in the second sentence of the "**DISPOSAL:**" paragraph of the "**STORAGE AND DISPOSAL**" section.

Revisions to 12-oz Box Only

1. "**LEFT SIDE PANEL**"

   i For the reasons discussed under 3ii above, delete "CAN KILL IN ONE FEEDING*" and the asterisk from the sentence "Rats and mice ... after feeding begins".

   ii Delete "SOLVING AMERICA'S RODENT PROBLEMS FOR 50 YEARS" and "*(KILLING MICE AND RATS IN AMERICA FOR 50 YEARS)*". Both claims are absolutely false for 3282-81, which has been registered for only 10 years, and for the active ingredient Brodifacoum, which has been registered in the U.S. for nearly 21 years. The claim also is false for d-Con anticoagulant baits, the oldest of which was registered in 1951. While it might be true that d-Con baits of some sort have been killing rodents in the U.S. for 50 years, the proposed claims, as worded, would be misleading even if that were their intended meaning.

Revisions of 3-oz Bait Tray

1. "**FRONT PANEL** "

   i Delete "CAN KILL IN ONE FEEDING*", and delete the asterisk from the sentence "Rats and mice ... after feeding begins".

   Because it is illegal to sell the bait trays individually and the trays must be placed in tamper-resistant bait stations when used in locations where children otherwise could have access to them, there seem to be no good reasons for having any promotional claims on the label for the bait trays.

If you have questions about this letter, you may reach Grace M. Robiou at (703) 305-1016.

Sincerely,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

F:\USER\GROBIOU\CORRESPONDENCE\Bromadiolone\3282-81.wpd

DP BARCODE: D254942

CASE: 027444 DATA PACKAGE RECORD DATE: 04/06/99
SUBMISSION: S559909 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 300 ADMN-LBL REV AMND NO DATA
RANKING : 5 POINTS ()
CHEMICALS: 112701 Brodifacoum (ANSI) 00.0050%

ID#: 003282-00081 D-CON READY MIXED GENERATION II
COMPANY: 003282 RECKITT & COLMAN INC, HOUSEHOLD PRODUCTS DIVISION
PRODUCT MANAGER: 04 TINA LEVINE 703-308-7055 ROOM: CM2 219
PM TEAM REVIEWER: GRACE ROBIOU 703-305-1016 ROOM: CM2 203
RECEIVED DATE: 03/12/99 DUE OUT DATE: 06/10/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 254942 EXPEDITE: Y DATE SENT: 04/06/99 DATE RET.: / /
CHEMICAL: 112701 Brodifacoum (ANSI)
DP TYPE: 001
CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 05/21/99
DIV : RD	/ /	/ /	NEGOT DATE: / /
BRAN: IRB	/ /	/ /	PROJ DATE: / /
SECT: PM04	/ /	/ /	
REVR : Lwp	4/6/99	5/25/99 OBJ	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Bill--

Revised labeling for d-Con Mixed Baitbits.

Last accepted label for this product is 1/28/99.

Note that revised labeling has also been submitted for 3282-74 and 3282-65.

Enclosed: cover letter, revised label.

See jacket for rest.

Thank you.
Grace

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

IRB BRANCH REVIEW - TSS

Record Number(s)

D254942

IN 4/6/99 OUT 5/25/99

EFFICACY

FILE OR REG. NO. 3282-81

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED

DATE OF SUBMISSION 3/10/99

DATE SUBMISSION ACCEPTED 4/6/99

TYPE PRODUCTS(S): I, D, H, F, N, R_x S

DATA ACCESSION NO(S). no new efficacy data

PRODUCT MGR. NO. 04

PRODUCT NAME(S) d-CON READY MIXED GENERATION II

COMPANY NAME Reckitt & Colman Company, Inc.

SUBMISSION PURPOSE amend labeling

CHEMICAL & FORMULATION 0.005% Brodifacoum crumbled bait in 3-oz bait travs

Efficacy Review: d-CON READY MIXED GENERATION II, 3282-81
Reckitt & Colman Company Inc.
Montvale, NJ 07645-1575

200.0 INTRODUCTION

200.1 Uses

3282-81 is a 0.005% Brodifacoum dry bait in 3-oz bait trays conditionally registered to control Norway rats, roof rats, and house mice

> "in and around homes, industrial, commercial, agricultural and public buildings ... [and] in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings."

200.2 Background Information

See efficacy reviews of 1/18/89, 7/16/90, 10/15/90, and 1/30/96 for 3282-81, along with other information in the product's jackets.

The current submission is dated 3/10/99. The materials from that submission that were routed to me include a cover letter and proposed revised labeling. The letter does not discuss the label revisions beyond stating that the labels are patterned after a label that EPA accepted for 3282-66 on 1/5/99. The letter also refers to a telephone conversation between its author, R&C's Bob Fellows, and Dan Peacock of IRB, to whom Fellows' letter was addressed.

R&C took about a year rather than the allotted 90 days to submit proposed revised labeling in response to PR Notice 94-7, which was issued on 9/16/94 and mailed to registrants in October of 1994. R&C did not submit proposed revised labels which addressed 94-7 issues on 11/8/95, just before more than a month's worth of government furloughs, snow days, and holidays in November and December of 1995 and January of 1996. (See efficacy review of 1/30/96 for an accounting of the time lost to various causes.) When we finally got back to work on a sustained basis in mid-January of 1996, I gave priority to the d-Con rodenticide baits so that R&C might be able to ship compliant labeling by the date (3/16/96) indicated in PR Notice 94-7 (see efficacy review of 1/30/96). Dan Peacock also gave those products high priority and put together letters of 2/1/96 which "ACCEPTED with COMMENTS" the labeling proposed by R&C on 11/8/95. The extent to which the proposed labeling had to change varied from product to product.

Due to backlogs accumulated during the furlough period and subsequent regulatory and organizational upheavals, we have not typically been able to turn R&C's subsequent labeling

submissions around very rapidly. The label for 3282-81 was revised in 1997 without an efficacy review. On 12/4/98, Dan Peacock passed along comments from the efficacy review of 1/12/98 for 3282-66 which also were relevant to 3282-81. He subsequently accepted labeling for 3282-81 on 1/28/99, but Fellows followed that action with the submission of 3/12/99 and, perhaps, an intervening telephone call.

201.0 DATA SUMMARY

No reports of efficacy data were submitted. Efficacy data relevant to 3282-81 are discussed in the efficacy reviews of 5/14/90 and 7/16/90. In the latter review, I accepted rat and mouse efficacy data for 3282-66. In that same review, I rejected the rat efficacy data submitted for 3282-81 because the bait was poorly accepted by most subjects and composite bait acceptance scores for the replicates were 28.1% and 18.1%, well below the 33% criterion. There also were 3 survivors (all males) among the 40 rats exposed to the toxic bait in these choice-test replicates.

The efficacy review of 10/15/90 discussed results of two additional replicates of rat efficacy trials with what was claimed to be the 3282-81 product. In these trials, composite bait acceptance scores were 40.3% and 45.0%, with all bait-exposed animals dying. However, there were 3 extremely marginal feeders (<5% acceptance). As the identity of the test material to the current composition of 3282-81 was not clearly established, the efficacy data discussed in the efficacy review were not accepted. To this day, it appears that the registrant has failed to establish this link and, therefore, that the rat claims made for 3282-81 technically still are not supported.

The relatively poor acceptance of 3282-81 may have been due to the fact that it consists of crumbled 3282-74 pellets (see efficacy review of 1/18/89). 3282-81 was created to be a Brodifacoum-containing counterpart to d-Con's "READY MIXED" Warfarin-containing bait, 3282-4 when the company replaced its Warfarin line with Brodifacoum baits. An important difference between the two products is that the well-accepted 3282-4 was largely a mixture of whole grains while 3282-81 consists of crumbled pellets which would be expected to be inefficient for rats to eat and not particularly attractive to them.

For reregistration, new efficacy data will have to be generated this product if d-Con wishes to retain any sort of single-feeding claim for these products. If any of the Phase I reformulation requirements (indicator dye and bittering agent) from the Rodenticide Cluster

Reregistration Eligibility Decision (RED) which pertains to Brodifacoum and 5 other compounds remain in force following the ongoing "Stakeholder" meetings, this product will have to be reformulated and tested for efficacy. Currently, this product contains a dye but no bittering agent.

The proposed revised labeling submitted includes labels for 3-oz bait trays, label panels for boxes which would hold 4 such trays (12-oz box) or 16 trays (3-lb box), and additional label panels which seem to pertain only to the 12-oz box.

The front panel common to the 12-oz and 3-lb boxes includes two objectionable promotional claims: "Flavor attractive to mice and rats" and "CAN KILL IN ONE FEEDING".

Considering the aforementioned efficacy data situation for 3282-81, the "Flavor attractive" claim seems exaggerative. I discussed the claim in the efficacy review of 1/30/96. The registrant was required to delete it via EPA's letter of 2/1/96.

For nearly two decades, we have "gone round and round" with d-Con people on the asterisked "CAN KILL IN ONE FEEDING" claim which, by itself, is misleading. In the past, we have allowed, for d-Con products, use of a modified version of the typical single-feeding claim for Brodifacoum baits. However, our trust in this regard has been abused by their overemphasis of the "CAN KILL IN ONE FEEDING" part at the expense of the text which makes the statement much less misleading. I have felt for some time that the best way for us to handle the matter is to deny the "CAN KILL IN ONE FEEDING" part entirely. Under "CONCLUSIONS", I summarize the issues for the registrant. EPA's letter of 1/28/99 removed "CAN KILL IN ONE FEEDING" and the asterisk from the label accepted on that date. See jackets for this and other d-Con Brodifacoum baits (3282-65, 3282-66, and 3282-74) for further discussions of this type of claim. See especially the efficacy review of 11/10/93 and our letter to the registrant of that same date for 3282-74 as well as the efficacy review of 1/12/98 for 3282-81.

The "**DIRECTIONS FOR USE**" section on the proposed revised box label incorporates the bait-protection text indicated in PR Notice 94-7 and is appropriately organized. There also is an appropriate qualification statement ("... 3 to 12 rats") for the 12-oz box.

Under "**APPLICATION DIRECTIONS:**", the directions "**To Control House Mice:**" have been modified unacceptably to read as shown immediately below.

"Open tray and place at 8 to 12 foot intervals indoors and against the outside walls of buildings of infested areas. Maintain a supply of fresh bait for at least 15 days."

The text for the same portion of the label accepted on 1/28/99 reads as shown immediately below.

"Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days."

I do not know about what, if anything, Fellows and Peacock spoke on 2/25/99, but I doubt that Peacock suggested changing this text in the manner proposed by R&C. The new text seems to negate the bait station requirements which appear elsewhere on the label and reads like a prescription for exposing young children and dogs of all ages to Brodifacoum. Not only does the proposed new text imply that the bait placements may be unprotected, each of these placements would consist of 3 oz. of bait rather than the typical 1/4-1/2 oz.

A 3-oz placement would include 4.25 mg of Brodifacoum, enough to kill a dog and also individuals of many species of wildlife. The typical placement sizes for house mice would only include 0.35-0.7 mg of toxicant. While the current label allows up to 2-oz of bait (about 2.8 mg of toxicant) per placement for controlling house mice, those placements are to be made only "at points of extremely high mouse activity." At such points, the mice might leave little for nontargets to eat, but the same could not be said for a 3-oz placement made at a locus where only about 1-4 ounce was taken by mice. (All of this exposure discussion would be moot if we could count on users of d-Con baits to place them in secured tamper-resistant baits stations, but such is not the case. Still, much bait would be wasted if individual placements were 3-oz rather than 1/4-1/2 oz.)

The "indoors and against the outside walls of buildings" text comes from page 114 of the Rodenticide Cluster RED where it was placed because EEB personnel believed that its adoption would lead to less secondary poisoning of wildlife than the current "in and around ... buildings" language. The substitution was supposed to be made under "**USE RESTRICTIONS:**" rather than in one part of the "**APPLICATION DIRECTIONS:**" but the RED is not very clear on that point.

As all of the cluster RED seems to be up in the air while the Stakeholder meetings are being held, I do not feel obligated to accept any text imposed by it at this time. In any event, I would not accept such text when it was placed inappropriately.

There is no indication on the proposed revised box label that any graphics are to be associated with the "**DIRECTIONS FOR USE**". We prohibited use of graphics for this product via our letter of 2/1/96 because: (a) no graphics appeared in the proposed revised labeling submitted on 11/8/95, and (b) the 6 pictures that have been used on labels for d-Con rat baits show bait placements that are not in tamper-resistant bait stations. So as not to have the label's requirements negated by the traditional 6,000-words' worth of pictures, we prohibited use of graphics. Had the company proposed to use appropriate graphics, we would have accepted them.

Via our letter of 12/4/98, we repeated the prohibition against use of unreviewed graphics for 3282-81. R&C has objected to this prohibition publicly (at the registrant's "Dye and Bittering Agents" meeting on 2/19/99) and in writing. In his letter of 1/8/99 regarding 3282-81, Fellows stated the following:

> "The goal of our use of graphics is to ensure that the user follows the use directions. The graphics on the product label demonstrate the appropriate placement of the product and proper use of tamper resistant bait stations. This is consistent with the Agency's and Industry's objective to promote proper use practices of Rodenticides. We kindly request that you reconsider your recommendation to remove the graphics."

The statement in our letters of 2/1/96 and 12/4/98 was "Do not include any graphics with these directions." That was a requirement, not a "recommendation". R&C has not taken the requirement to heart. In a visit to a RITE-AID store in the Crystal City area of Arlington County, VA, on 5/20/99, I found several boxes of 3282-81 for sale (for $5.19 and $5.39). All boxes bore the 6 graphics traditionally used on labels for d-Con rat baits along with 94-7 bait-protection text.

One of the graphics used on labels of d-Con rat baits shows bait being placed into a bait station, while another shows a bait station being locked. However, there is no evidence of baffling or bait-containment structures within the bait station. Other graphics traditionally used on printed

labels for 3282-81 show a bait station under a storage shelf in what appears to be a wooden-walled structure, a "lean board" (with no nailing evident) positioned against an indoor wall of a similar structure, a person opening a bait tray using a bare hand, and a Norway rat feeding from an opened bait tray that has been placed in the open. Assertions to the effect that such graphics show only

> "appropriate placement of the product and proper use of tamper resistant bait stations placements"

clearly are not valid.

The "**12 OZ. BOX RIGHT SIDE PANEL**" proposed on 3/12/99 bears only claims which appear to be acceptable and disclaimer information to which I have no objections.

The "**12 OZ. BOX LEFT SIDE PANEL**" proposed on 3/12/99 bears some acceptable claims and some to which I have strong objections. The latter include:

1. a reprise of "CAN KILL IN ONE FEEDING" with two sets of asterisks (the second being for "Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins"); and

2. "SOLVING AMERICA'S RODENT PROBLEMS FOR 50 YEARS", for which R&C might substitute "*(KILLING MICE AND RATS IN AMERICA FOR 50 YEARS)*.

The first of these in discussed already. The "50 YEARS" claims, or variants thereof, have been used and disallowed for years. The problem with the claims is that they are absolutely false for the d-Con line of Brodifacoum baits, the first of which were registered on 11/18/81 (3282-65 and 3282-66) and were not marketed extensively until nearly 5 years later. In fact, the first Warfarin product ever registered under the d-Con name was accepted on 6/8/51. A few years ago, I indicated that a "40 YEARS" claim referring to d-Con the company rather than implying the specific product could be accepted; but now the company name on the label has been changed from "The d-Con Company" to Reckitt & Colman Inc.

The registrant's name and the production establishment number do not appear on any label panel that applies to the 3-lb box. Except as a header, the registration number also is missing from panels that apply to the 3-lb box.

The label proposed for the 3-oz bait tray is acceptable to me except for its inclusion of the "CAN KILL IN ONE FEEDING*" claim. Because it is illegal to sell the bait trays individually and the trays must be placed in tamper-resistant bait stations when used in locations where children otherwise could have access to them, there seem to be no good reasons for having any promotional claims on the label for the bait trays.

202.0 CONCLUSIONS

Modify the proposed revised labeling that you submitted for this product on March 10, 1999, as indicated below.

I. 12-oz and 3-lb Boxes

A. Entire labels

The registrant's name, the product's registration number, and the establishment number must appear on the label for the 3-lb box as well as on the label for the 12-oz box.

As you have proposed no graphics for inclusion on the box labels, none may appear on them. We previously have forbidden the use of unreviewed graphics for this product via our letters of February 1, 1996, and December 4, 1998. In your letter of January 8, 1999, you erroneously characterized this prohibition as a "recommendation" and asserted that

> The graphics on the product label demonstrate the appropriate placement of the product and proper use of tamper resistant bait stations.

We strongly disagree with that characterization. One of the graphics used on labels of d-Con rat baits shows a bait tray being placed into a bait station, while another shows a bait station being locked. However, there is no evidence of baffling or bait-containment structures within the bait station. The entrances to the bait station being loaded appear to be very close to the likely destination of the bait tray -- close enough for a small child to reach through the rodent entry ports and get to the bait tray. Consequently, the bait station depicted in those graphics falls far short of being tamper-resistant, whether or not it is locked and secured. See PR Notice 94-7 for a list of criteria for tamper-resistant bait stations.

Other graphics traditionally used on printed labels for 3282-81 show a bait station under a storage shelf in what appears to be a wooden-walled structure, a "lean board" positioned against an indoor wall of a similar structure, a person opening a bait tray using a bare hand, and, on the front panel, a Norway rat feeding from an opened bait tray that appears to have been placed out in the open.

In one way or another, the graphics that you have included on labels for your rat baits tend to detract from the required bait-protection text which appears on the label. During the many years that such graphics have appeared on d-Con labels, there have been thousands of reported exposure incidents involving your products. Whether those graphics have affected the occurrence of exposure incidents involving d-Con rat baits in any way is something that we might discuss, but it seems doubtful that either you or we would have a definitive answer.

We have no objections to graphics that illustrate appropriate product use. Considering the use and incident history of rodenticide baits, we must review such graphics before they may be added to product labeling.

Our letters of February 1, 1996 and December 4, 1998, stated "Do not include any graphics with these directions." Because proposed labeling was "ACCEPTED with COMMENTS" via our letter of February 1, 1996, you were given no leeway to modify labeling contrary to the stipulations of that letter. Although we required many significant changes label text via our letter of February 1, 1996, we chose the "ACCEPTED with COMMENTS" route as a favor to you because the date (March 16, 1996) after which you could ship only labeling compliant with PR Notice 94-7 was fast approaching. You may recall that your company took more than a year to submit proposed revised labeling in response to that PR notice and that we gave your submission prompt attention, considering that we lost some 24 working days during that time period to government shut-downs due to furloughs, bad weather, and Federal holidays.

B. "**FRONT LABEL**"

1. Delete the claim "Flavor attractive to mice and rats". This claim may be false and is certainly misleading as all registered anticoagulant baits

must pass tests similar to those required for this bait, which neither rats nor mice accepted as well as they did our challenge diet.

A bait acceptance problem with this product was discovered when we reviewed rat efficacy data submitted (MRID Nos. 413082-01 and 415247-01) for 3282-81 in 1990. Data (MRID No. 416037-01) submitted subsequently in that year suggested better bait acceptance by rats, but the test bait was not sufficiently linked to this product's formulation. Therefore, the claims made for this bait are not supported by data which demonstrate adequate bait acceptance by rats. See our letters of October 30, 1990, and February 1, 1996, for more discussion of this point.

2. Delete the claim "CAN KILL IN ONE FEEDING" and the asterisk which precedes the sentence "Rats and mice may ... begins." In the past, your company has abused the asterisked claim by overemphasizing the "CAN KILL IN ONE FEEDING" portion and, at times, even moving the remaining portion to a different label panel. We have concluded that the only solution to this problem is to ban use of the "CAN KILL IN ONE FEEDING" portion of the claim entirely. By themselves, those words comprise

> A true statement used in such a way as to give a false or misleading impression to the purchaser.

Such statements are prohibited under 40 CFR, §156.10(a)(5)(vii).

The "CAN KILL IN ONE FEEDING" claim is misleading. Although a single day's feeding might load a rat or mouse with enough poison to cause its death, that death is not going to occur for several more days, during some of which time the lethally dosed rodents will feed relatively normally. An ordinary person who reads "CAN KILL IN ONE FEEDING" is likely to expect to see dead rodents in one day and may use less bait than is needed to control the infestation.

B. "**BACK LABEL**"

1. The proposed change to the "**To Control House Mice:**" portion of the "**APPLICATION DIRECTIONS:**" subsection of the "**DIRECTIONS FOR USE**" is not

acceptable. The new text implies open-air placements "indoors and against the outside walls of buildings", and all such placements would grossly exceed the amount of bait needed to control house mice. The proposed new directions might encourage nontarget exposures of young children, pets, and nontarget wildlife to Brodifacoum bait.

The "**To Control House Mice:**" text must continue to read as shown immediately below.

> **To Control House Mice:** Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

2. Change "contained" to "container" in the second sentence of the "**DISPOSAL:**" paragraph of the "**STORAGE AND DISPOSAL**" section.

II. <u>12-oz Box Only</u>

A. "**<u>LEFT SIDE PANEL</u>**"

1. For the reasons discussed under I.B.2. above, delete "CAN KILL IN ONE FEEDING*" and the asterisk from the sentence "Rats and mice ... after feeding begins".

2. Delete "SOLVING AMERICA'S RODENT PROBLEMS FOR 50 YEARS" and "*(KILLING MICE AND RATS IN AMERICA FOR 50 YEARS)*". Both claims are absolutely false for 3282-81, which has been registered for only 10 years, and for the active ingredient Brodifacoum, which has been registered in the U.S. for nearly 21 years. The claim also is false for d-Con anticoagulant baits, the oldest of which was registered in 1951. While it might be true that d-Con baits of some sort have been killing rodents in the U.S. for 50 years, the proposed claims, as worded, would be misleading even if that were their intended meaning.

III. 3-oz Bait Tray

A. "**FRONT PANEL**"

1. Delete "CAN KILL IN ONE FEEDING*", and delete the asterisk from the sentence "Rats and mice ... after feeding begins".

   Because it is illegal to sell the bait trays individually and the trays must be placed in tamper-resistant bait stations when used in locations where children otherwise could have access to them, there seem to be no good reasons for having any promotional claims on the label for the bait trays.

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
May 25, 1999

5-559909

RECKITT & COLMAN

Mr. Dan Peacock
Insecticide / Rodenticide Branch
U.S. Environmental Protection Agency
Crystal Mall, Building 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

March 10, 1999

Subject: **d-Con Mouse Prufe II; EPA 3282-65**
d-Con Bait Pellets II; EPA 3282-74
d-Con Ready Mixed Baitbits; EPA 3282-81

Dear Mr. Peacock:
As per the conversation we had on February 25, 1999, enclosed please find three (3) copies of draft labelling for the subject products. These labels have been revised to reflect all required label language consistent with current regulations.
As we agreed, the following information is enclosed:
1) Revised draft labels for

- d-Con Mouse Prufe II; EPA 3282-65
- d-Con Bait Pellets II; EPA 3282-74
- d-Con Ready Mixed Baitbits; EPA 3282-81

2) A copy of EPA approval dated 1/5/99 for d-Con Bait Pellets; EPA 3282-66. This label text is consistent with the label language for the subject registrations. We have duplicated the text on the enclosed draft labels.

3) Copy of last label amendment submission(s) to EPA for the subject products specific to EPA Reg. No. 3282-65 and 3282-74.

This information is being provided, to assist you in an effort to expedite the label review for these submissions.
Thank you for your assistance. Please contact me if you have any questions or comments.
Regards,

Bob Fellows

Bob Fellows
Reckitt & Colman Inc.
Tel: 973/686-7389
Fax: 973/686-7396-5
email: bob.fellows@reckitt.com

Working Copy (jacket)

12 OZ. AND 3 LB. OUTER BOX
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

Flavor attractive to mice and rats

Satisfaction guaranteed or your money back

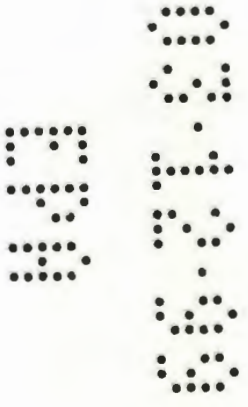
CAN KILL IN ONE FEEDING
*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

4 READY-TO-USE BAITS FILLED TRAYS
NET CONTENTS 4/3.0 OZ. (85g) NET WT. 12 OZ. (340g)

16 READY-TO-USE BAITS FILLED TRAYS
NET WT. 3 LBS.



12 OZ. AND 3 LB. OUTER BOX
BACK LABEL

d-CON® READY MIXED GENERATION II

KILLS MICE AND RATS

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions. Do not apply this product by any method not specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where mice or rats will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT:"**).

APPLICATION DIRECTIONS:
(FOR 12 OZ. BOX ONLY): The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1 - 4 bait trays per placement. Space placements at intervals of 15 - 30 feet in infested areas. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and place at 8 to 12 foot intervals indoors and against the outside walls of buildings of infested areas. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:
This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

STORAGE AND DISPOSAL:

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

DISPOSAL: Do not reuse empty container. Securely wrap contained and any unused bait in newspaper and discard in trash.

12 OZ. BOX RIGHT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS MICE AND RATS

Kills
Warfarin-Resistant
House Mice and
Warfarin-Resistant
Norway Rats

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1

SATISFACTION
GUARANTEED OR
YOUR MONEY BACK

12 OZ. BOX LEFT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS MICE AND RATS

CAN KILL IN ONE FEEDING*

*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins

MADE IN THE USA

SOLVING AMERICA'S RODENT PROBLEMS
FOR 50 YEARS

(KILLING MICE AND RATS IN AMERICA
FOR 50 YEARS)

SATISFACTION
GUARANTEED OR
YOUR MONEY BACK

Distributed by:
Household Products Division
Reckitt & Colman Inc.
Wayne, NJ 07474

3 OZ. BAIT TRAY
FRONT PANEL

d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

Ready-To-Use Bait Tray

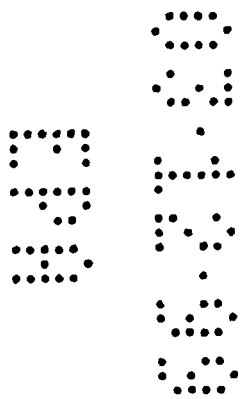
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

CAN KILL IN ONE FEEDING
*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

NET WT. 3 OZ. BAIT TRAY (85g)



3 OZ. BAIT TRAY - BACK PANEL

d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

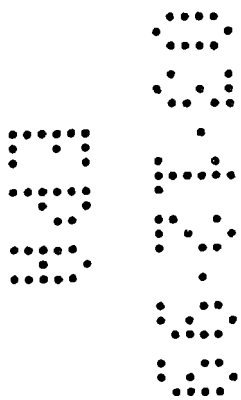
ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%

INERT INGREDIENTS: 99.995%

TOTAL 100.000%



Distributed by:
Household Products Division
Reckitt & Colman Inc. Wayne, NJ 07474

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1

Z 487 320 785

US Postal Service

Receipt for Certified Mail

No Insurance Coverage Provided.

Do not use for International Mail *(See reverse)*

Sent to Reckitt & Colman	
Street & Number	
Post Office, State, & ZIP Code	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to Whom & Date Delivered	
Return Receipt Showing to Whom, Date, & Addressee's Address	
TOTAL Postage & Fees	$
Postmark or Date	

PS Form **3800**, April 1995

Stick postage stamps to article to cover First-Class postage, certified mail fee, and charges for any selected optional services *(See front).*

1. If you want this receipt postmarked, stick the gummed stub to the right of the return address leaving the receipt attached, and present the article at a post office service window or hand it to your rural carrier *(no extra charge).*

2. If you do not want this receipt postmarked, stick the gummed stub to the right of the return address of the article, date, detach, and retain the receipt, and mail the article.

3. If you want a return receipt, write the certified mail number and your name and address on a return receipt card, Form 3811, and attach it to the front of the article by means of the gummed ends if space permits. Otherwise, affix to back of article. Endorse front of article **RETURN RECEIPT REQUESTED** adjacent to the number.

4. If you want delivery restricted to the addressee, or to an authorized agent of the addressee, endorse **RESTRICTED DELIVERY** on the front of the article

5. Enter fees for the services requested in the appropriate spaces on the front of this receipt. If return receipt is requested, check the applicable blocks in item 1 of Form 3811.

6. Save this receipt and present it if you make an inquiry

102595-98-M-0548

PS Form **3800**, April 1995 *(Reverse)*

5-555500 300
18

CERTIFIED MAIL

JAN 28 1999

Reckitt & Colman Inc.
225 Summit Avenue
Monvale, NJ 07645-1575

Attention: Ms. Ruth Trager

Subject: d-Con Pellets Generation II
EPA Registration No. 3282-81
Your letter of January 8, 1999

Dear Ms. Trager:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following change and submit one (1) final copy to us before you ship your product:

1. On the front panel of the box label, replace

"CAN KILL IN ONE FEEDING
* Rats and mice may consume a lethal dose in one feeding with dead rodents appearing 4 or 5 days after feeding begins"

with

"Rats and mice may consume a lethal dose in one feeding with dead rodents appearing 4 or 5 days after feeding begins"

This registration will be subject to cancellation in accordance with FIFRA sec. 6(e) if you do not comply with these conditions. Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Enclosure: Stamped Label

F:\USER\GROBIOU\CORRESPONDENCE\Brodifacoum\3282-81(2).wpd

Working Copy

12 OZ. AND 3 LB. OUTER BOX
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

CAN KILL IN ONE FEEDING ?

*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JAN 28 1999
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 3282-81

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

4 READY-TO-USE BAITS FILLED TRAYS
NET CONTENTS 4/3.0 OZ. (85g) NET WT. 12 OZ. (340g)

16 READY-TO-USE BAITS FILLED TRAYS
NET WT. 3 LBS.

12 OZ. AND 3 LB. OUTER BOX
BACK LABEL

d-CON® READY MIXED GENERATION II

KILLS MICE AND RATS
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT:"**).

APPLICATION DIRECTIONS:
(FOR 12 OZ. BOX ONLY: The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.)

To Control Norway and Roof Rats: Place 1 - 4 bait trays per placement. Space placements at intervals of 15 - 30 feet in infested areas. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:
This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

STORAGE AND DISPOSAL:

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

DISPOSAL: Do not reuse empty container. Securely wrap contained and any unused bait in newspaper and discard in trash.

12 OZ. BOX RIGHT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS MICE AND RATS

Kills
Warfarin-Resistant
House Mice and
Warfarin-Resistant
Norway Rats

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1; 2393-WI-1

SATISFACTION
GUARANTEED OR
YOUR MONEY BACK

12 OZ. BOX LEFT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS MICE AND RATS

CAN KILL IN ONE FEEDING*

*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins

MADE IN THE USA

d-CON BAITS:
KILLING RATS AND MICE IN AMERICA
FOR 50 YEARS

SATISFACTION
GUARANTEED OR
YOUR MONEY BACK

Distributed by:
Household Products Division
Reckitt & Colman Inc.
Wayne, NJ 07474

3 OZ. BAIT TRAY
FRONT PANEL

d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

READY-TO-USE BAIT TRAY

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

CAN KILL IN ONE FEEDING
*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

NET WT. 3 OZ. BAIT TRAY (85g)

3 OZ. BAIT TRAY
BACK PANEL

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF REACH OF CHILDREN.

Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistant bait boxes.

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

Distributed by:
Household Products Division
Reckitt & Colman Inc. Wayne, NJ 07474

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1; 2392-WI-1

S 555500

308

RECKITT & COLMAN

Mr. Dan Peacock
Insecticide / Rodenticide Branch
U.S. Environmental Protection Agency
Crystal Mall, Building 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

January 8, 1999

RE: d-Con Ready Mixed Generation II; EPA 3282-81
Label Revisions - Your letter of December 4, 1998

Dear Mr. Peacock:
Enclosed please find three (3) copies of draft labelling for d-Con Ready Mixed Generation II, EPA 3282-81, which have been revised to reflect the changes requested in your December 4th letter (copy attached) and PR Notice 94-7.
The labels have been revised as follows;

EPA Comment A 1:

Center " **DIRECTIONS FOR USE** "

RESPONSE:

The " **DIRECTIONS FOR USE** " heading has been centered. All other subheadings remain left justified.

EPA Comment A2:

Move and slightly alter the statement " If trays are not fed from for 5 consecutive days, relocate them to places where rodent activity exists and where placements consistent with the requirements of this label can be made ".

RESPONSE

Under APPLICATION DIRECTIONS, the statement " If trays are not fed from for 5 consecutive days..... can be made " has been moved to the control of rats area and slightly altered, as directed.

✓ **EPA Comment A2 cont.:**

Do not include any graphics with these directions.

RESPONSE

The goal of our use of graphics is to ensure that the user follows the use directions. The graphics on the product label demonstrate the appropriate placement of the product and proper use of tamper resistant bait stations. This is consistent with the Agency's and Industry's objective to promote proper use practices of Rodenticides. We kindly request that you reconsider your recommendation to remove the graphics.

✓ **EPA Comment A3:**

Remove the subheading " **PLACEMENT** " under application directions.

RESPONSE

The subheading " **PLACEMENT** " has been deleted.

EPA Comment A4:

On the front panel of the box, replace " Rats and mice will die within 4 or 5 days after feeding begins ", with " Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins ".

RESPONSE

" CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days
after feeding begins "

has been replaced with

" CAN KILL IN ONE FEEDING*
*Rats and mice may consume a lethal dose in
one feeding with first dead rodents appearing 4
or 5 days after feeding begins "

EPA Comment B:

Organize the heading and subheadings in " STORAGE AND DISPOSAL " in the manner indicated.

RESPONSE

B. " **STORAGE AND DISPOSAL** " has been centred;

Storage:
Disposal:

appear as separate subheadings.

Thank you for your assistance. Please contact me if you have any questions or comments.

Regards,

Bob Fellows

Bob Fellows
Reckitt & Colman Inc.
Tel: 973/686-7389
Fax: 973/686-7396-5
email: bob.fellows@reckitt.com

Z 487 320 795

US Postal Service

Receipt for Certified Mail

No Insurance Coverage Provided.

Do not use for International Mail *(See reverse)*

Sent to Rockwell & Golman	
Street & Number Ruth Trager	
Post Office, State, & ZIP Code	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to Whom & Date Delivered	
Return Receipt Showing to Whom, Date, & Addressee's Address	
TOTAL Postage & Fees	$
Postmark or Date	

PS Form **3800**, April 1995

Stick postage stamps to article to cover First-Class postage, certified mail fee, and charges for any selected optional services *(See front).*

1. If you want this receipt postmarked, stick the gummed stub to the right of the return address leaving the receipt attached, and present the article at a post office service window or hand it to your rural carrier *(no extra charge).*

2. If you do not want this receipt postmarked, stick the gummed stub to the right of the return address of the article, date, detach, and retain the receipt, and mail the article.

3. If you want a return receipt, write the certified mail number and your name and address on a return receipt card, Form 3811, and attach it to the front of the article by means of the gummed ends if space permits. Otherwise, affix to back of article. Endorse front of article **RETURN RECEIPT REQUESTED** adjacent to the number.

4. If you want delivery restricted to the addressee, or to an authorized agent of the addressee, endorse **RESTRICTED DELIVERY** on the front of the article.

5. Enter fees for the services requested in the appropriate spaces on the front of this receipt. If return receipt is requested, check the applicable blocks in item 1 of Form 3811.

6. Save this receipt and present it if you make an inquiry.

102595-98-M-0548

PS Form **3800**, April 1995 *(Reverse)*

~~5552288 357~~
S 555497 360

CERTIFIED MAIL

DEC - 4 1998

Reckitt & Colman Inc.
225 Summit Avenue
Monvale, NJ 07645-1575

Attention: Ms. Ruth Trager

Subject: d-Con Pellets Generation II
EPA Registration No. 3282-81
Our letter of February 13, 1997

According to our files, we never received a copy of your final revised labeling following the specifications made on our letter of February 13, 1997. Within 30 days of receipt of this letter, submit three (3) copies of your current label. The following changes should also appear in your submission:

A. Modify the proposed revised labeling submitted for this product on July 15, 1996, to read as indicated below. Note that some of these changes also were required by our letter of February 1, 1996.

✓1. On the back panel of the label for the 12-oz outer box, organize the heading and subheadings in the "**DIRECTIONS FOR USE**" in the manner indicated below (and also in PR Notice 94-7 and in our letter of February 1, 1996). The major heading "**DIRECTIONS FOR USE**" must be centered so that it is clear that the subheadings "**READ THIS LABEL:**", "**IMPORTANT**", "**USE RESTRICTIONS**", "**SELECTION OF TREATMENT AREAS**", and "**APPLICATION DIRECTIONS**" are sub-ordinate to "**DIRECTIONS FOR USE**" and are all parts of that section.

Where the text on your label differs from that indicated below, change the text on your label.

"**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label...

IMPORTANT: Do not expose children, pets, or other....

USE RESTRICTIONS: This product may be....

SELECTION OF TREATMENT AREAS: Determine .....

APPLICATION DIRECTIONS:

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. If trays are not fed from for 5 consecutive days, relocate them to other places where rat activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than ½ of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Note that it is necessary to move and slightly alter the sentence

"If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made."

This is because the sentence applies only to the control of commensal rats since the directions for controlling house mice do not call for the use of the contents of an entire tray at any one locus.

Preserve this format and content when labels are printed. Do not include any graphics with these directions.

✓ 2. The "subsubheading" "**PLACEMENT:**" which appears in your proposed revised box label under "**APPLICATION DIRECTIONS:**" should be deleted as it is unnecessary. Both of the set-in paragraphs under "**PLACEMENT:**" have their own headings already, and those headings ("**To Control Norway and Roof Rats:**" and "**To Control House Mice:**") are sufficient when considered in context. Make sure that these two paragraphs are the only ones set in when labels are printed.

✳3. On the front panel of the box label, replace

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days
after feeding begins"

with

"Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

The statement that you seek to make is false and misleading. Not all rats and mice exposed to the product will die, and those that do die will not all die within 4 or 5 days after feeding begins. We apologize for having accepted (or acquiesced to) somewhat similar statements in the past.

Make this same substitution on the left side panel of the box label and on the front panel of the label for 3-oz bait trays.

✓ 4. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim as indicated above.

✓ B. Organize the heading and subheading in "STORAGE AND DISPOSAL" in the manner indicated below. The major heading "STORAGE AND DISPOSAL" must be centered so that it is clear that "Storage" and "Disposal" are subheadings.

STORAGE AND DISPOSAL

Storage: Store only in original container, in a dry place inaccessible to children and pets.

Disposal: Do not reuse empty container. Securely wrap contained and any unused bait in newspaper and discard in trash.

C. You requested to retain the stronger text, "May be harmful or fatal if swallowed." This text is acceptable at the present time. We will be studying the issue of the most appropriate text during the RED process. If any labeling changes are needed in the future, we will inform you.

If you have any questions, you may contact me at (703) 305-5407.

Sincerely,

Daniel B. Peacock
Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

F:\USER\GROBIOU\CORRESPONDENCE\Brodifacoum\3282-81.wpd

WORKING COPY

Incl. Comments + Concl.

Efficacy Review: d-CON PELLETS GENERATION II, 3282-66
Reckitt & Colman Inc.
Montvale, NJ 07645-1575

200.0 INTRODUCTION

200.1 Uses

0.005% Brodifacoum dry bait conditionally registered to control Norway rats, roof rats, and house mice

> "in and around homes, industrial, commercial, agricultural and public buildings. . . . in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings."

200.2 Background Information

See efficacy reviews of 12/29/88, 5/14/90, 7/16/90, and 1/30/96, along with other information in these products' jackets. Review of the "current" submission, dated 7/15/96, has been delayed for about a year because the submission was not given by Leonard Cole to Daniel Peacock when administrative responsibility for Brodifacoum was reassigned to Mr. Peacock early in FY '97. I located the submission in Mr. Cole's files on 1/6/98.. On 2/13/97, Mr. Peacock completed a similar action on a similarly-dated submission for a similar d-Con product: d-CON READY MIXED GENERATION II, 3282-81.

Reckitt and Colman's submission of 7/15/96 for 3282-66 consists of a cover letter and 5 copies of proposed labeling reportedly revised in response to EPA's letter of 2/1/96. In that letter, EPA responded to Reckitt & Colman's belated submission of 11/8/95 which had included proposed labeling

> "revised to include prescribed language as per PR Notice 94-7, the change in company name from 'The d-Con Company Inc.' to 'Household Products Division, Reckitt & Colman.' and label language that has been added as part of notifications."

PR Notice 94-7 was issued on 9/16/94 and was mailed to registrants of commensal rodenticide baits over the next month, with parties generally receiving the notice during October of 1994. Within 90 days of receipt of PR Notice 94-7, registrants of products affected by it were required to submit labels amended which included the bait protection statements prescribed by the notice. Therefore, Reckitt & Colman's initial response to PR Notice 94-7 was 9 months too late.

On 2/1/96, EPA "ACCEPTED with COMMENTS" the labeling submitted on 11/8/95. This meant that Reckitt & Colman had a month and a half to come up with printed labeling that was consistent with what EPA accepted on 2/1/96 and in compliance with PR Notice 94-7. The jacket for 3282-66 does not show any submission of final printed labeling despite a request in the first paragraph of EPA's letter of 2/1/96 for something of that nature.

201.0 DATA SUMMARY

No reports of efficacy data were submitted. Efficacy data relevant to this product are discussed in the efficacy reviews of 5/14/90 and 7/16/90. In the latter review, I accepted rat and mouse efficacy data for 3282-66.

At the time of reregistration, new efficacy data will have to be generated for both products if d-Con wishes to retain any sort of single-feeding claim for these products. If SRRD goes through with its plans to demand reformulation of commensal rodenticide baits to add a bittering agent and an "indicator dye", this product will have to be reformulated and tested for efficacy. The bait currently lacks a bittering agent. Although the bait contains a dye, it might lack an "indicator dye" of the sort that SRRD envisions.

The proposed revised labeling submitted includes labels for 3-oz bait trays and labels for boxes which would hold 4 such trays. In its letter of 7/15/96, Reckitt & Colman takes issue with some of the changes that EPA directed in its letter of 2/1/96, but claims to have complied with others. In fact, Reckitt & Colman did not make all of the required changes that its letter of 7/15/96 fails to discuss. (Unfortunately, we failed to notice similar problems in the submission of 7/15/96 for 3282-81. Daniel Peacock handled that submission without an efficacy review, but I signed the letter on 2/13/97.)

As was the case with their submission of 11/8/95, the **"DIRECTIONS FOR USE"** on the labeling submitted on 7/15/96 are not properly organized in that the subheadings **"READ THIS LABEL"**, **"IMPORTANT"**, **"USE RESTRICTIONS"**, **"SELECTION OF TREATMENT AREAS"**, and **"APPLICATION DIRECTIONS"** are presented in parallel (i.e., with equal emphasis) to the main heading **"DIRECTIONS FOR USE"**. As a consequence, the **"DIRECTIONS FOR USE"** section appears to begin and end with the "It is a violation of Federal law . . . labeling" sentence. How to correct this problem was emphasized in EPA's letter of 2/1/96.

The issue of organization of the use directions can become a big deal for rodenticide baits when registrants break up

the directions between label panels, thereby separating the baiting instructions (**"APPLICATION DIRECTIONS:"**) from the bait protection statements (**"IMPORTANT:"**) and the **"USE RESTRICTIONS:"**. When formatted as Reckitt & Colman has done for this product, the **"DIRECTIONS FOR USE"** section technically lacks many of the components required for it in 40 CFR, §156.10.

There is another lingering problem with the use directions plus another which Reckitt & Colman has introduced. These are discussed under "CONCLUSIONS".

The proposed revised box label includes fewer promotional claims than did the box label proposed on 11/8/95. The claims that remain either were acceptable to begin with or have been modified somewhat or entirely in accordance with EPA's letter of 2/1/96.

The claim which remains problematical is the modified single-feeding claim. EPA's letter of 2/1/96 directed that ~~the claim~~ proposed by Reckitt & Colman --

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days" --

be changed to

"Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

Reckitt & Colman responded by proposing the claim

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days
after feeding begins" --

That statement is that it is false and misleading. Not all rats and mice exposed to the product will die as some of them will not eat a sufficient amount of bait. Those that do die will not all die within 4 or 5 days after feeding begins. Sadly, we have accepted the statement now sought for 3282-66 on the label accepted for 3282-81 on 2/13/97 and, in fact, had accepted the version proposed on 11/8/95 for d-Con products in earlier years. However, we should not extend the problem by continuing to accept false and misleading text. We should repeat the change required by our letter of 2/1/96 for 3282-66. We also should take some corrective action with respect to 3282-81, probably on a next-printing basis.

The proposed revised bait label for bait trays now includes

a **"DIRECTIONS FOR USE"** section which reads as shown immediately below.

"DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually."

done!

This is the text which EPA's letter of 2/1/96 required.

The tray label also bears the inappropriate single-feeding claim which must be modified.

Although the "anticoagulant cluster RED" might be issued at any moment and is expected to prescribe its own set of label changes, I feel that IRB should respond to Reckitt & Colman as indicated below with respect to 3282-66. I also feel that we should attempt to fix things for 3282-81. We have no guarantee of a timely release of the RED nor do we know whether it will endure in its original form as, from what I know of the RED's expected contents, it is likely to engender considerable opposition in the rodenticide industry.

202.0 CONCLUSIONS

3282-66

Modify the proposed revised labeling submitted for this product on July 15, 1996, to read as indicated below. Note that some of these changes also were required by our letter of February 1, 1996.

A1) On the back panel of the label for the 12-oz outer box, organize the heading and subheadings in the manner indicated below (and also in PR Notice 94-7 and in our letter of February 1, 1996). The major heading **"DIRECTIONS FOR USE"** must be centered so that it is clear that the subheadings **"READ THIS LABEL:"**, **"IMPORTANT"**, **"USE RESTRICTIONS"**, **"SELECTION OF TREATMENT AREAS"**, and **"APPLICATION DIRECTIONS"** are subordinant to **"DIRECTIONS FOR USE"** and are all parts of that section. Where the text on your label differs from that indicated below, change the text on your label.

"DIRECTIONS FOR USE

It is violation of Federal law to use this

product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Pellets Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen.

Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT"**).

APPLICATION DIRECTIONS:

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. If trays are not fed from for 5 consecutive days, relocate them to other places where rat activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when labels are printed. Do not include any graphics with these directions. Note that it is necessary to move and slightly alter the sentence

"If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements

consistent with the requirements of this label can be made."

This is because the sentence applies only to the control of commensal rats since the directions for controlling house mice do not call for the use of the contents of an entire tray at any one locus.

A2.

The "subsubheading" **"PLACEMENT:"** which appears in your proposed revised box label under **"APPLICATION DIRECTIONS:"** should be deleted as it is unnecessary. Both of the set-in paragraphs under **"PLACEMENT:"** have their own headings already, and those headings (**"To Control Norway and Roof Rats:"** and **"To Control House Mice:"**) are sufficient when considered in context. Make sure that these two paragraphs are the only ones set in when labels are printed.

3. On the front panel of the box label, replace

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days after feeding begins"

with

"Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

The statement that you seek to make is false and misleading. Not all rats and mice exposed to the product will die, and those that do die will not all die within 4 or 5 days after feeding begins. We apologize for having accepted (or acquiesced to) somewhat similar statements in the past.

Make this same substitution on the left side panel of the box label and on the front panel of the label for 3-oz bait trays.

4. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim as indicated above.

3282-81

At the next printing of this product's labeling, make the changes indicated below.

1. On the back panel of the box label, organize the heading and subheadings in the **"DIRECTIONS FOR USE"** in the

manner indicated below (and also in PR Notice 94-7 and in our letter of February 1, 1996). The major heading **"DIRECTIONS FOR USE"** must be centered so that it is clear that the subheadings **"READ THIS LABEL:"**, **"IMPORTANT"**, **"USE RESTRICTIONS"**, **"SELECTION OF TREATMENT AREAS"**, and **"APPLICATION DIRECTIONS"** are subordinant to **"DIRECTIONS FOR USE"** and are all parts of that section. Where the text on your label differs from that indicated below, change the text on your label.

"DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal

buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT"**).

APPLICATION DIRECTIONS:

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations. [This paragraph applies to the 12-oz, 4-tray package but not to the 3-lb package.]

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. If trays are not fed from for 5 consecutive days, relocate them to other places where rat activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. Collect and dispose of all dead animals and leftover bait properly.

> To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when labels are printed. Do not include any graphics with these directions.

Note that it is necessary to move and slightly alter the sentence

> "If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made."

This is because the sentence applies only to the control of commensal rats since the directions for control of house mice do not call for the use of the contents of an entire tray at any one locus.

2. The "subsubheading" **"PLACEMENT:"** which appears in your proposed revised box label under **"APPLICATION DIRECTIONS:"** should be deleted as it is unnecessary. Both of the set-in paragraphs under **"PLACEMENT:"** have their own headings already, and those headings (**"To Control Norway and Roof Rats:"** and **"To Control House Mice:"**) are sufficient when considered in context. Make sure that these two paragraphs are the only ones set in when labels are printed.

3.b. On the front panel of the box label, replace

> "CAN KILL IN ONE FEEDING
> Rats and mice will die within 4 or 5 days after feeding begins"

with

> "Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

The statement on your current label is false and misleading. Not all rats and mice exposed to the product will die, and those that do die will not all die within 4 or 5 days after feeding begins. We apologize for having accepted the proposed statement in the past.

Make this same substitution on the left side panel of the box label and on the front panel of the label for 3-oz bait trays.

3. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim as indicated above.

[PEG: The labeling submitted for 3282-66 also includes departures from our previously prescribed text for the **"PRECAUTIONARY STATEMENTS"** and **"ENVIRONMENTAL HAZARDS"** sections. I have not addressed these changes in this review. The response that Dan prepared for the labeling of 3282-81 concentrated on the precautionary text (which possibly was the reason why I did not catch the problems with the claims and use directions). The company's arguments on the "harmful or fatal" issue are interesting. In any event, I am passing the jacket for 3282-81 along to you so that you can have a look at the response of 2/13/97 for that product.]

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
January 12, 1998

An Extra for 3282-81

IRB BRANCH REVIEW - TSS

Record Number(s)

D241950

IN 1/6/98 OUT 1/12/98

EFFICACY

FILE OR REG. NO. 3282-66

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 7/16/96

DATE OF SUBMISSION 7/15/96

DATE SUBMISSION ACCEPTED 1/6/98

TYPE PRODUCTS(S): I, D, H, F, N, R$_x$ S

DATA ACCESSION NO(S). no new efficacy data

PRODUCT MGR. NO. 04

PRODUCT NAME(S) d-CON PELLETS GENERATION II

COMPANY NAME Rechitt & Colman Inc.

SUBMISSION PURPOSE amend label

CHEMICAL & FORMULATION 0.005% Brodifacoum pelleted bait in 3-oz bait trays

Efficacy Review: d-CON PELLETS GENERATION II, 3282-66
Reckitt & Colman Inc.
Montvale, NJ 07645-1575

200.0 INTRODUCTION

200.1 Uses

0.005% Brodifacoum dry bait conditionally registered to control Norway rats, roof rats, and house mice

> "in and around homes, industrial, commercial, agricultural and public buildings. . . . in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings."

200.2 Background Information

See efficacy reviews of 12/29/88, 5/14/90, 7/16/90, and 1/30/96, along with other information in these products' jackets. Review of the "current" submission, dated 7/15/96, has been delayed for about a year because the submission was not given by Leonard Cole to Daniel Peacock when administrative responsibility for Brodifacoum was reassigned to Mr. Peacock early in FY '97. I located the submission in Mr. Cole's files on 1/6/98. On 2/13/97, Mr. Peacock completed a similar action on a similarly-dated submission for a similar d-Con product: d-CON READY MIXED GENERATION II, 3282-81.

Reckitt and Colman's submission of 7/15/96 for 3282-66 consists of a cover letter and 5 copies of proposed labeling reportedly revised in response to EPA's letter of 2/1/96. In that letter, EPA responded to Reckitt & Colman's belated submission of 11/8/95 which had included proposed labeling

> "revised to include prescribed language as per PR Notice 94-7, the change in company name from 'The d-Con Company Inc.' to 'Household Products Division, Reckitt & Colman.' and label language that has been added as part of notifications."

PR Notice 94-7 was issued on 9/16/94 and was mailed to registrants of commensal rodenticide baits over the next month, with parties generally receiving the notice during October of 1994. Within 90 days of receipt of PR Notice 94-7, registrants of products affected by it were required to submit labels amended which included the bait protection statements prescribed by the notice. Therefore, Reckitt & Colman's initial response to PR Notice 94-7 was 9 months too late.

On 2/1/96, EPA "ACCEPTED with COMMENTS" the labeling submitted on 11/8/95. This meant that Reckitt & Colman had a month and a half to come up with printed labeling that was consistent with what EPA accepted on 2/1/96 and in compliance with PR Notice 94-7. The jacket for 3282-66 does not show any submission of final printed labeling despite a request in the first paragraph of EPA's letter of 2/1/96 for something of that nature.

201.0 DATA SUMMARY

No reports of efficacy data were submitted. Efficacy data relevant to this product are discussed in the efficacy reviews of 5/14/90 and 7/16/90. In the latter review, I accepted rat and mouse efficacy data for 3282-66.

At the time of reregistration, new efficacy data will have to be generated for both products if d-Con wishes to retain any sort of single-feeding claim for these products. If SRRD goes through with its plans to demand reformulation of commensal rodenticide baits to add a bittering agent and an "indicator dye", this product will have to be reformulated and tested for efficacy. The bait currently lacks a bittering agent. Although the bait contains a dye, it might lack an "indicator dye" of the sort that SRRD envisions.

The proposed revised labeling submitted includes labels for 3-oz bait trays and labels for boxes which would hold 4 such trays. In its letter of 7/15/96, Reckitt & Colman takes issue with some of the changes that EPA directed in its letter of 2/1/96, but claims to have complied with others. In fact, Reckitt & Colman did not make all of the required changes that its letter of 7/15/96 fails to discuss. (Unfortunately, we failed to notice similar problems in the submission of 7/15/96 for 3282-81. Daniel Peacock handled that submission without an efficacy review, but I signed the letter on 2/13/97.)

As was the case with their submission of 11/8/95, the "**DIRECTIONS FOR USE**" on the labeling submitted on 7/15/96 are not properly organized in that the subheadings "**READ THIS LABEL**", "**IMPORTANT**", "**USE RESTRICTIONS**", "**SELECTION OF TREATMENT AREAS**", and "**APPLICATION DIRECTIONS**" are presented in parallel (i.e., with equal emphasis) to the main heading "**DIRECTIONS FOR USE**". As a consequence, the "**DIRECTIONS FOR USE**" section appears to begin and end with the "It is a violation of Federal law . . . labeling" sentence. How to correct this problem was emphasized in EPA's letter of 2/1/96.

The issue of organization of the use directions can become a big deal for rodenticide baits when registrants break up the directions between label panels, thereby separating the baiting instructions ("**APPLICATION DIRECTIONS:**") from the bait protection statements ("**IMPORTANT:**") and the "**USE RESTRICTIONS:**". When formatted as Reckitt & Colman has done for this product, the "**DIRECTIONS FOR USE**" section technically lacks many of the components required for it in 40 CFR, §156.10.

There is another lingering problem with the use directions plus another which Reckitt & Colman has introduced. These are discussed under "CONCLUSIONS".

The proposed revised box label includes fewer promotional claims than did the box label proposed on 11/8/95. The claims that remain either were acceptable to begin with or have been modified somewhat or entirely in accordance with EPA's letter of 2/1/96.

The claim which remains problematical is the modified single-feeding claim. EPA's letter of 2/1/96 directed that the claim proposed by Reckitt & Colman --

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days" --

be changed to

"Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

Reckitt & Colman responded by proposing the claim

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days
after feeding begins" --

That statement is that it is false and misleading. Not all rats and mice exposed to the product will die as some of them will not eat a sufficient amount of bait. Those that do die will not all die within 4 or 5 days after feeding begins. Sadly, we have accepted the statement now sought for 3282-66 on the label accepted for 3282-81 on 2/13/97 and, in fact, had accepted the version proposed on 11/8/95 for d-Con products in earlier years. However, we should not extend the problem by continuing to accept false and misleading text. We should repeat the change required by our letter of 2/1/96 for 3282-66. We also should take some corrective action with respect to 3282-81, probably on a next-printing basis.

The proposed revised bait label for bait trays now includes a "**DIRECTIONS FOR USE**" section which reads as shown immediately below.

"**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually."

This is the text which EPA's letter of 2/1/96 required.

The tray label also bears the inappropriate single-feeding claim which must be modified.

Although the "anticoagulant cluster RED" might be issued at any moment and is expected to prescribe its own set of label changes, I feel that IRB should respond to Reckitt & Colman as indicated below with respect to 3282-66. I also feel that we should attempt to fix things for 3282-81. We have no guarantee of a timely release of the RED nor do we know whether it will endure in its original form as, from what I know of the RED's expected contents, it is likely to engender considerable opposition in the rodenticide industry.

202.0 CONCLUSIONS

3282-66

Modify the proposed revised labeling submitted for this product on July 15, 1996, to read as indicated below. Note that some of these changes also were required by our letter of February 1, 1996.

1. On the back panel of the label for the 12-oz outer box, organize the heading and subheadings in the "**DIRECTIONS FOR USE**" in the manner indicated below (and also in PR Notice 94-7 and in our letter of February 1, 1996). The major heading "**DIRECTIONS FOR USE**" must be centered so that it is clear that the subheadings "**READ THIS LABEL:**", "**IMPORTANT**", "**USE RESTRICTIONS**", "**SELECTION OF TREATMENT AREAS**", and "**APPLICATION DIRECTIONS**" are subordinant to "**DIRECTIONS FOR USE**" and are all parts of that section. Where the text on your label differs from that indicated below, change the text on your label.

"**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Pellets Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along

walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see "**IMPORTANT**").

APPLICATION DIRECTIONS:

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. If trays are not fed from for 5 consecutive days, relocate them to other places where rat activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when labels are printed. Do not include any graphics with these

directions. Note that it is necessary to move and slightly alter the sentence

> "If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made."

This is because the sentence applies only to the control of commensal rats since the directions for controlling house mice do not call for the use of the contents of an entire tray at any one locus.

The "subsubheading" "**PLACEMENT:**" which appears in your proposed revised box label under "**APPLICATION DIRECTIONS:**" should be deleted as it is unnecessary. Both of the set-in paragraphs under "**PLACEMENT:**" have their own headings already, and those headings ("**To Control Norway and Roof Rats:**" and "**To Control House Mice:**") are sufficient when considered in context. Make sure that these two paragraphs are the only ones set in when labels are printed.

2. On the front panel of the box label, replace

> "CAN KILL IN ONE FEEDING
> Rats and mice will die within 4 or 5 days after feeding begins"

with

> "Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

The statement that you seek to make is false and misleading. Not all rats and mice exposed to the product will die, and those that do die will not all die within 4 or 5 days after feeding begins. We apologize for having accepted (or acquiesced to) somewhat similar statements in the past.

Make this same substitution on the left side panel of the box label and on the front panel of the label for 3-oz bait trays.

3. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim as indicated above.

3282-81

At the next printing of this product's labeling, make the changes indicated below.

1. On the back panel of the box label, organize the heading and subheadings in the "**DIRECTIONS FOR USE**" in the manner indicated below (and also in PR Notice 94-7 and in our letter of February 1, 1996). The major heading "**DIRECTIONS FOR USE**" must be centered so that it is clear that the subheadings "**READ THIS LABEL:**", "**IMPORTANT**", "**USE RESTRICTIONS**", "**SELECTION OF TREATMENT AREAS**", and "**APPLICATION DIRECTIONS**" are subordinant to "**DIRECTIONS FOR USE**" and are all parts of that section. Where the text on your label differs from that indicated below, change the text on your label.

"**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see "**IMPORTANT**").

APPLICATION DIRECTIONS:

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations. [This paragraph applies to the 12-oz, 4-tray package but not to the 3-lb package.]

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. If trays are not fed from for 5 consecutive days, relocate them to other places where rat activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when labels are printed. Do not include any graphics with these directions.

Note that it is necessary to move and slightly alter the sentence

"If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made."

This is because the sentence applies only to the control of commensal rats since the directions for control of house mice do not call for the use of the contents of an entire tray at any one locus.

The "subsubheading" "**PLACEMENT:**" which appears in your proposed revised box label under "**APPLICATION DIRECTIONS:**" should be deleted as it is unnecessary. Both of the set-in paragraphs under "**PLACEMENT:**" have their own headings already, and those headings ("**To Control Norway and Roof Rats:**" and "**To Control House Mice:**") are sufficient when considered in context. Make sure that these two paragraphs are the only ones set in when labels are printed.

2. On the front panel of the box label, replace

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days after feeding begins"

with

"Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

The statement on your current label is false and misleading. Not all rats and mice exposed to the product will die, and those that do die will not all die within 4 or 5 days after feeding begins. We apologize for having accepted the proposed statement in the past.

Make this same substitution on the left side panel of the box label and on the front panel of the label for 3-oz bait trays.

3. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim as indicated above.

[PEG: The labeling submitted for 3282-66 also includes departures from our previously prescribed text for the "**PRECAUTIONARY STATEMENTS**" and "**ENVIRONMENTAL HAZARDS**" sections. I have not addressed these changes in this review. The response that Dan prepared for the labeling of 3282-81 concentrated on the precautionary text (which possibly was the reason why I did not catch the problems with the claims and use directions). The company's arguments on the "harmful or fatal" issue are interesting. In any event, I am passing the jacket for 3282-81 along to you so that you can have a look at the response of 2/13/97 for that product.]

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
January 12, 1998

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357/18

FEB 13 1997

Reckitt & Colman Inc.
225 Summit Ave.
Montvale, NJ 07645-1575

Attention: Ms. Ruth Trager

Subject: d-Con Ready Mixed Generation II
EPA Registration No. 3282-81
Your letter of July 15, 1996

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following changes and submit one (1) copy to us before you ship your product:

A. 12 oz. and 3 lb. Outer Box Label

1. Under "SELECTION OF TREATMENT AREAS", place a period after "(see "IMPORTANT:").

2. Under "CAUTION", place a period after "Wash hands after handling bait".

B. 3 oz. Bait Tray Label

1. Under "CAUTION", place a period after "Wash hands after handling bait".

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

William W. Jacobs, PhD
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

Enclosures: 1. Stamped Label
2. A-79 Enclosure

Peacock WP#11:A:\Talon\3282-81.FEB:305-5407,-6600:2/13/97

12 OZ. AND 3 LB. OUTER BOX
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

ACCEPTED with COMMENTS In EPA Letter Dated FEB-13 1997 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 3282-81

CAN KILL IN ONE FEEDING
Mice and rats will die within
4 or 5 days after feeding begins

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

4 READY-TO-USE BAITS FILLED TRAYS
NET CONTENTS 4/3.0 OZ. (85g) NET WT. 12 OZ. (340g)

16 READY-TO-USE BAITS FILLED TRAYS
NET WT. 3 LBS.

12 OZ. AND 3 LB. OUTER BOX
BACK LABEL

d-CON® READY MIXED GENERATION II

KILLS MICE AND RATS
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT:"**)

APPLICATION DIRECTIONS:

(FOR 12 OZ. BOX ONLY: The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.)

PLACEMENT:

To Control Norway and Roof Rats: Place 1 - 4 bait trays per placement. Space placements at intervals of 15 - 30 feet in infested areas. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

STORAGE AND DISPOSAL: Store in original container in a dry place inaccessible to children and pets. Do not reuse empty container. Securely wrap container and any unused bait in newspaper and discard in trash.

MADE IN THE USA

d-CON BAITS: KILLING MICE AND RATS IN AMERICA FOR OVER 40 YEARS

SATISFACTION GUARANTEED OR YOUR MONEY BACK

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

Distributed by: Household Products Division
Reckitt & Colman Inc. Montvale, NJ 07645

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1; 2393-WI-1

3 OZ. BAIT TRAY
FRONT PANEL

d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

READY-TO-USE BAIT TRAY

ACCEPTED with COMMENTS In EPA Letter Dated
FEB 13 1997
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 3282-81

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

CAN KILL IN ONE FEEDING
Mice and rats will die within
4 or 5 days after feeding begins

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS 99.995%
TOTAL 100.000%

NET WT. 3 OZ. BAIT TRAY (85g)

3 OZ. BAIT TRAY
BACK PANEL

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
KEEP OUT OF REACH OF CHILDREN.

Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistant bait boxes.

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

Distributed by:
Household Products Division
Reckitt & Colman Inc. Montvale, NJ 07645

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1; 2392-WI-1

Company Data Report

Company No.: 3282

Name: RECKITT & COLMAN INC, HOUSEHOLD PRODUCTS DIVISION
ATTN: EPA REGULATORY DEPT

Address: 225 SUMMITT AVE
MONTVALE, NJ 07645
USA

Contact: Phone:

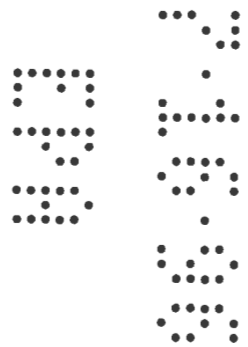
Agent: N
Consortium: N
Undeliverable: N

Company Types	Active Flag
Manufacturer	Y

RECKITT & COLMAN

July 15, 1996

Mr. Robert Forrest (PM-14)
Insecticide / Rodenticide Branch
Registration Division, H7504C
U.S. Environmental Protection Agency
Crystal Mall, Building #2, Room 219
1921 Jefferson Davis Highway
Arlington, VA 22202



Re: **d-CON Ready Mixed Generation II**
EPA Reg. No. 3282-81
Response to your letter dated February 1, 1996

Dear Mr. Forrest:

In response to your letter, enclosed are 5 copies of a draft label for d-CON Ready Mixed Generation II, EPA Reg. No. 3282-81. The label has been revised as follows:

EPA Comment A.:

The Agency has requested that the precautionary statement "May be harmful or fatal if swallowed" be modified to "May be harmful if swallowed."

RESPONSE:
The precautionary statement "May be harmful or fatal if swallowed" has been left unchanged.

Reckitt & Colman Inc. shares EPA's continued concern for the safe use of rodenticides as stated in PR Notice 94-7. Reckitt & Colman wants to insure the isolation of commensal rodenticides from children, dogs, other pets, domestic animals and nontarget wildlife. The statement "May be harmful or fatal if swallowed" has been required on the labels for many years. We feel that if the "or fatal" is removed from this statement, the purchasers of the rodenticides may assume that the product has in some way become "safer" or "less toxic" and these purchasers may not take as much care or precautions in the placement of the product and accidents, illnesses, deaths or nontarget exposures may result from the use of such rodenticides. As stated in PR Notice 94-7, more than 10,000 rodenticide incidents were reported in the American Association of Poison Control Center's National Data Collection System in 1988 and nearly 90% of the poison control cases involved children under 6 years of age and more than 80% of the nontarget animal

exposures are dog incidents. We feel that the removal of "or fatal" would dilute the importance of PR Notices 83-5 and 94-7. If the purchasers of commensal rodenticides were following the bait protection practices directed by the labels, there would have been no need for PR Notices 83-5 and 94-7. Since the high number of rodenticide-caused accidents and illnesses have occurred while "or fatal" has been prescribed on the label, removal of these words may lead to an even greater number of accidents and illnesses.

Although the acute oral toxicity category for 0.005% brodifacoum is Category III, "CAUTION", and "or fatal" is inconsistent with Category III, acute toxicity tests are not the only information that may be used to determine the precautionary statements. According to CFR 40 §156.10 (h) (2) (i) (A) "Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. ..." (B) "The following table depicts **typical** precautionary statements. These statements **must** be modified or **expanded** to reflect specific hazards." Accident history or field studies may be used to modify precautionary statements. We believe that real life exposure scenarios, such as that referenced above, should be used to justify keeping the "or fatal" in the precautionary statement "May be harmful or fatal if swallowed."

EPA Comment B. :

1. The use directions have been modified as per the letter.

2. "Can Kill In One Feeding*
*Mice will die within 4 or 5 days"

has been replaced with: "Can Kill In One Feeding*
*Mice will die within 4 or 5 days after feeding begins."

3. The claim "Flavor attractive to mice and rats" has been deleted.

4. The sentence "d-CON Pellets Generation II can kill in one feeding when used as directed" has been deleted.

5. The claim "Solving America's Rodent Problems For Over 40 Years" has been changed to "d-CON BAITS: Killing Mice in America For Over 40 Years".

6. Same as Item 2. above.

7. The **"DIRECTIONS FOR USE"** section has been added to the 3 oz. bait tray as directed.

EPA Comment C.:
The last sentence of the **"Environmental Hazards"** section has been revised as directed.

EPA Comment D:

The "Storage and Disposal" statements has been revised as directed.

Thank you for your attention to this submission. We look forward to receiving a "stamped accepted" label as quickly as possible.

If you have any questions, you can contact me at 1-800-526-0321, ext. 7767.

Sincerely,

Ruth Trager

Ruth Trager
Senior Regulatory Affairs Associate

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number: 204446

Section I

1. Company/Product Number: 3282-81
2. EPA Product Manager: Robert A. Forrest
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): d-CON Ready Mixed Generation II
   PM#: 14
5. Name and Address of Applicant *(Include ZIP Code)*:
   Household Products Division
   Reckitt & Colman Inc.
   225 Summit Avenue
   Montvale, NJ 07645
   ☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No. _____
   Product Name _____

Section II

☐ Amendment - Explain below
☐ Resubmission in response to Agency letter dated _____.
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION - Addition of the following statements: "Solving America's Rodent Problems For Over 40 Years"; "Made in the USA"; Addition of the EPA Est. No. 475-MS-1.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) of Retail Container
5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (Specify) _____

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Ruth Trager	Sr. Regulatory Affairs Associate	201-573-5792

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Ruth Trager
3. Title: Sr. Regulatory Affairs Associate
4. Typed Name: Ruth Trager
5. Date: October 6, 1995
6. Date Application Received (Stamped)

EPA Form 8570-1 (Rev. 12-90) **Previous editions are obsolete.** White - EPA File Copy (original) Yellow - Applicant copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Specify the net contents of all retail containers for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., New products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

RECKITT & COLMAN

October 9, 1995

Mr. Robert A. Forrest (PM-14)
Insecticide / Rodenticide Branch
Registration Division, H7505C
U.S. Environmental Protection Agency
Crystal Mall, Building #2, Room 219
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: **d-CON Ready Mixed Generation II**
EPA Reg. No. 3282-81
Notification of additional label language

Dear Mr. Forrest:

This letter is to notify you of the following additional label language for the above product:

Addition of the statements: "Solving America's Rodent Problems for Over 40 Years"
"Made in the USA";

Addition of the EPA Est. No. 475-MS-1.

In support of this notification, enclosed is EPA Form 8570-1, Application for Pesticide Notification, OPP Identifier No. 204446. Please note these additions accordingly in our file.

If you have any questions, you can contact me at 1-800-526-0321, ext. 5792.

Thank you.

Sincerely,

Ruth Trager

Ruth Trager
Sr. Regulatory Affairs Associate

RECKITT & COLMAN INC.
225 Summit Avenue, Montvale, NJ 07645-1575 201-573-5700

February 1, 1996 356 5-497519 18

Reckitt & Colman Inc.
225 Summit Ave.
Montvale, NJ 07645-1575

Attention: Ms. Ruth Trager

Subject: d-Con Ready Mixed Generation II
EPA Registration No. 3282-81
Your amended application of November 8, 1995

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following changes and submit one (1) copy to us before your ship product:

A. In your precautionary statements, we have required, in the past, the following text:

CAUTION

May be harmful or fatal if swallowed.

However, the second precautionary statement would appear to be inconsistent with the Regulations [40 CFR 156.10(h)] for the following reasons:

1. A product supported by an acute oral toxicity study in Category III requires the signal word, "CAUTION" and the precautionary statement: "May be **harmful** if swallowed."

2. A product supported by an acute oral toxicity study in Category II requires the signal word, WARNING" and the precautionary statement: "May be **fatal** if swallowed."

According to our files, the acute oral toxicity study supporting this 0.005% Brodifacoum product is in Toxicity Category III. Therefore, in order to make the labeling for this product consistent with the regulations, you should modify the above precautionary statements as follows:

CAUTION

May be **harmful** if swallowed.

B. Modify the proposed revised labeling that you submitted for this product on November 11, 1995, as indicated below.

1. On the labels for the 12-oz and 3-lb outer containers, organize the heading and subheadings in the "**DIRECTIONS FOR USE**" in the manner indicated below (and in PR Notice 94-7) and modify this entire section to read as shown below. Note that some of the text in the "**USE RESTRICTIONS**", "**SELECTION OF TREATMENT AREAS**", and "**APPLICATION DIRECTIONS**" sections must be changed.

"**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see "**IMPORTANT**").

APPLICATION DIRECTIONS:

[The paragraph immediately below applies to the 12-oz box but not to the 3-lb box.]

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

For Rats and Mice: Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when labels are printed. Do not include any graphics with these directions.

2. On the front panels of the outer box labels, replace

CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days

with

Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Make this same substitution on the left side panel of the 12-oz box label and from wherever else it might appear on the labels for all outer packaging used for this product.

3. Delete from the front panels of the outer box labels the claim "flavor attractive to mice and rats". From the data that have been submitted to us and linked to this product (MRID Nos. 413082-01 and 415247-01), it does not appear that this bait is very attractive to CD Strain Norway rats, at least. Data submitted subsequently (MRID No. 416037-01) suggested better

acceptance by Wistar strain rats, but we were unable at the time that the submission was reviewed to establish a link between the bait used and the 3282-81 product. Consequently, we have not accepted that study for 3282-81, and the rat claims for this product technically are not supported (see our letter of October 30, 1990). Until this matter is resolved, claims to the effect that the 3282-81 product is especially attractive to target rodents are not acceptable.

4. Delete from the back panel of the 12-oz box label (and from wherever it might appear on the 3-lb box) the sentence

   d-CON Pellets Generation II can kill in one feeding when used as directed.

5. As written, the claim, on the box labels, which reads

   "SOLVING AMERICA'S RODENT
   PROBLEMS FOR OVER 40 YEARS"

   is false and misleading. This product has not been registered for 40 years. What seems to be true is that d-CON baits have been used to control commensal rodents for more than 40 years. Therefore, an acceptable claim would be

   "d-CON BAITS: KILLING RATS AND MICE
   IN AMERICA FOR MORE THAN 40 YEARS".

6. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim to read

   "Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

   As these trays are not to be sold individually, we question the need for this claim on the label for the bait trays.

7. On the back panel of the label for the bait tray, replace

   See outer box for complete Directions for Use.

   with the text shown at the beginning of the next page.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

Note that bait trays sold individually would be misbranded because they would lack complete "**DIRECTIONS FOR USE**" and "**STORAGE AND DISPOSAL**" text. As the 3-oz contents are below the minimum requirement for a single placement of "loose" anticoagulant bait used to control commensal rats, an individually-sold container of that amount could not bear claims for controlling Norway rats or roof rats.

When setting up labels for printing, make sure that logos and other not-required items do not obscure or detract from required label statements.

C. In accordance with PR Notice 93-8, change the last sentence in your "Environmental Hazards" section from "Keep out of any body of water." to "Do not apply directly to water."

D. Revise your "STORAGE AND DISPOSAL" statement as follows:

STORAGE AND DISPOSAL

Storage: Store only in original container, in a dry place inaccessible to children and pets.

Disposal: Do not reuse empty container. Securely wrap container and any unused bait in newspaper and discard in trash.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

Enclosures: 1. Stamped Label
2. A-79 Enclosure

Peacock WP#8:A:Brodifac\3282-81:305-5407,-6600:2/1/96

d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
12 OZ. AND 3 LB. OUTER BOX
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

d-CON®
READY MIXED GENERATION II

ACCEPTED
with COMMENTS
In EPA Letter Dated
FEB 1 1996

KILLS MICE AND RATS

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 3282-81

flavor attractive to mice and rats

CAN KILL IN ONE FEEDING
Mice and rats will die within 4 or 5 days

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS.....99.995%
TOTAL 100.000%

4 READY-TO-USE BAITS FILLED TRAYS
NET CONTENTS 4/3.0 OZ. (85g) NET WT. 12 OZ. (340g)

16 READY-TO-USE BAITS FILLED TRAYS
NET WT. 3 LBS.

d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
12 OZ. AND 3 LB. OUTER BOX
BACK LABEL

---

d-CON® READY MIXED GENERATION II

KILLS MICE AND RATS
d-CON Ready Mixed Generation II can kill in one feeding when used as directed. Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.
DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS: Place trays in or near points where you have seen mice or rat signs such as droppings, runways, burrows, or gnawing marks. Once areas requiring baiting have been identified, proceed as follows:

d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
12 OZ. AND 3 LB. OUTER BOX
BACK LABEL CONTINUED

APPLICATION DIRECTIONS:

1. Place one ready-to-use bait tray in each potential feeding location. Place trays in dark, out-of-the-way locations, where rodents are likely to find them.
   For House Mice: Use only one tray per location.
   For Norway and Roof Rats: Start with one tray per location. Add trays, up to a maximum of four per location, if you determine that there is high rat activity at the location.
2. For best results, leave trays undisturbed for at least two days after placement. However, if contents have been scattered or mostly consumed sooner, replace trays. Clean up spilled bait. Check bait every two days, replacing trays as needed or until signs of rodent activity cease. Trays not fed from for five consecutive days may be relocated as needed. When there are no longer any signs of rodent activity, dispose of trays properly.

For complete control, continue baiting for at least 15 days. If you are in an area where there is a danger of reinfestation from adjoining property, permanent bait stations should be maintained. Stations should be checked periodically.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
12 OZ. AND 3 LB. OUTER BOX
BACK LABEL CONTINUED

ENVIRONMENTAL HAZARDS:
This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

STORAGE AND DISPOSAL:
Store in original container in areas inaccessible to small children and pets. Bait that cannot be used according to label instructions must be disposed of according to applicable federal, state or local procedures.

MADE IN THE USA

SOLVING AMERICA'S RODENT PROBLEMS FOR OVER 40 YEARS

SATISFACTION GUARANTEED OR YOUR MONEY BACK

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

Distributed by: Household Products Division
Reckitt & Colman Inc. Montvale, NJ 07645

EPA Reg. No. 3282-81
EPA Est. No. 3282-OH-1; 475-MS-1; 2393-WI-1

d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
3 OZ. BAIT TRAY
FRONT PANEL

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d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

READY-TO-USE BAIT TRAY

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

CAN KILL IN ONE FEEDING

Mice and rats will die within 4 or 5 days

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS.....99.995%
TOTAL 100.000%

NET WT. 3 OZ. BAIT TRAY (85g)

d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
3 OZ. BAIT TRAY
BACK PANEL

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistant bait boxes.

KEEP OUT OF REACH OF CHILDREN.

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS.....99.995%

See outer box for complete Directions For Use.

Household Products Division
Reckitt & Colman Inc. Montvale, NJ 07645

EPA Reg. No. 3282-81
EPA Est. No. 3282-OH-1; 475-MS-1; 2392-WI-1

IRB BRANCH REVIEW - TSS

Record Number(s)

3282-66: D221426
3282-81: D221493

12/5/95
IN 12/6/95 OUT 1/30/96

EFFICACY

FILE OR REG. NO. as above

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 11/9/95

DATE OF SUBMISSION 11/8/95

DATE SUBMISSION ACCEPTED 12/5/95, 12/6/95

TYPE PRODUCTS(S): I, D, H, F, N, RX S

DATA ACCESSION NO(S). no new efficacy data

PRODUCT MGR. NO. 14

PRODUCT NAME(S) d-CON PELLETS GENERATION II
d-CON READY MIXED GENERATION II

COMPANY NAME Reckitt & Colman Company Inc..

SUBMISSION PURPOSE compliance with PR Notice 94-7

CHEMICAL & FORMULATION 0.005% Brodifacoum dry baits in 3-oz bait trays

Efficacy Review: d-CON PELLETS GENERATION II, 3282-66
d-CON READY MIXED GENERATION II, 3282-81
Reckitt & Colman Company Inc.
Montvale, NJ 07645-1575

200.0 INTRODUCTION

200.1 Uses

0.005% Brodifacoum dry baits conditionally registered to control Norway rats, roof rats, and house mice "in and around homes, industrial, commercial, agricultural and public buildings.

200.2 Background Information

See efficacy reviews of 12/29/88 and 7/16/90 for 3282-66 and efficacy reviews of 1/18/89, 7/16/90 and 10/15/90 for 3282-81, along with other information in these products' jackets.

The current submissions, both dated 11/8/95, consist of cover letters, amendment forms, and proposed labeling reportedly

> "revised to include prescribed language as per PR Notice 94-7, the change in company name from 'The d-Con Company Inc.' to 'Household Products Division, Reckitt & Colman.' and label language that has been added as part of notifications."

PR Notice 94-7 was issued on 9/16/94 and was mailed to registrants of commensal rodenticide baits over the next month, with parties generally receiving the notice during October of 1994. Within 90 days of receipt of PR Notice 94-7, registrants of products affected by it were required to submit labels amended which included the bait protection statements prescribed by the notice. Therefore, Reckitt & Colman appears to have responded more than 9 months too late. The company's tardiness alone accounts for more than half of the time period between the company's receipt of PR Notice 94-7 and the date, 3/16/96, after which no containers of affected products may be shipped without labels bearing text in compliance with that notice.

The period of time from receipt of submission to completion of this efficacy review (i.e., 11/9/95 to 1/30/96) actually has been shorter for these products than was the case for nearly all of the other products for which labels were submitted in response to PR Notice 94-7. I have moved these products ahead of many others in order to respond as quickly as I have. Some 70 of the 83 days from 11/9/95 to

1/30/96 were lost from possible review time for the reasons indicated below. This total includes the 27 days (11/9-12/6/95) which elapsed before the PM Team staff person routed the items to me for review. Note that the staff person was not available to work on this type of action for 14 of those 27 days.

WORKER NOT AVAILABLE FOR TYPE OF ACTIVITY	PRE-ROUTING	POST-ROUTING	TOTALS
Weekend Days	6	16	22
Holidays	2	3	5
Furloughed Days	3	13	16
Vacation Days	1	4	5
Compressed Days Off	2	3	5
Snow Days		4	4
TOTALS	14	43	57
Days Available to Administrative Reviewer	13		13
Days Not Available to Efficacy Reviewer			70
Days Available to Efficacy Reviewer			13
TOTAL DAYS			83

201.0 DATA SUMMARY

No reports of efficacy data were submitted. Efficacy data relevant to both products are discussed in the efficacy reviews of 5/14/90 and 7/16/90. In the latter review, I accepted rat and mouse efficacy data for 3282-66. In that same review, I rejected the rat efficacy data submitted for 3282-81 because the bait was poorly accepted by most subjects and composite bait acceptance scores for the replicates were 28.1% and 18.1%, well below the 33% criterion. There also were three survivors (all males) among the 40 rats exposed to the toxic bait in these choice-test replicates.

The efficacy review of 10/15/90 discusses results of two additional replicates of rat efficacy trials with what was claimed to be the 3282-81 product. In these trials, composite bait acceptance scores were 40.3% and 45.0%, with all bait-exposed animals dying. However, there were 3 extremely marginal feeders (<5% acceptance). As the

identity of the test material to the current composition of 3282-81 was not clearly established, the efficacy data discussed in the efficacy review were not accepted. To this day, it appears that the registrant has failed to establish this link and, therefore, that the rat claims made for 3282-81 technically still are not supported.

The relatively poor acceptance of 3282-81 may have been due to the fact that it consists of crumbled pellets (see efficacy review of 1/18/89). It appears that 3282-81 was created to be a Brodifacoum-containing counterpart to d-Con's "READY MIXED" Warfarin-containing bait, 3282-4, as the company was replacing its Warfarin line with Brodifacoum baits. An important difference between the two products is that the well-accepted 3282-4 was largely a mixture of whole grains while 3282-81 consists of crumbled pellets which would be expected to be inefficient for rats to eat and not particularly attractive to them.

At the time of reregistration, new efficacy data will have to be generated for both products if d-Con wishes to retain any sort of single-feeding claim for these products. On 8/21/95, Ruth Trager of Reckitt & Colman called me and left a Voice Mail message on the issue of test methods for the single-feeding claim. I left a recorded message for her on 8/23/95, but cannot find records of an actual conversation between us. At this point, I feel that d-Con's single-feeding claim should be brought into line with what is on the labels for other second-generation anticoagulant baits. There have been some problems with the relative emphasis of the "SINGLE-FEEDING" vs. the "4-or-5 days" parts of the claim.

The proposed revised labeling submitted includes, for each product, labels for 3-oz bait trays and labels for boxes which would hold 4 such trays (both products) or 16 trays (2-lb box for 3282-81 only).

The proposed revised box labels incorporate all of the bait-protection text indicated in PR Notice 94-7. However, the **"DIRECTIONS FOR USE"** sections are not properly organized in that the subheadings **"READ THIS LABEL"**, **"IMPORTANT"**, **"USE RESTRICTIONS"**, **"SELECTION OF TREATMENT AREAS"**, and **"APPLICATION DIRECTIONS"** are presented in parallel (i.e., with equal emphasis) to the main heading **"DIRECTIONS FOR USE"**. As a consequence, the **"DIRECTIONS FOR USE"** section appears to begin and end with the "It is a violation of Federal law . . . labeling" sentence.

Apart from the bait protection text, the use directions for these products depart from those typically used for anticoagulant baits claimed to control commensal rodents.

Some of these departures are related to the fact that the product comes in bait trays. Others seem to be related to the company's desires to market the product effectively and to communicate with potential users in relatively simple terms. While there are no a priori reasons to object to language modifications for such purposed, the alternative text must be examined carefully for missing elements, false or misleading statements, and/or text which contradicts or detracts in any way from required directions, restrictions, or precautions. In 1992, I performed a similar exercise for d-CON's Warfarin rat and mouse baits.

The proposed revised box labels include various promotional claims. These also must be examined carefully so that false statements are eliminated and misleading statements either are eliminated or modified so as to be appropriate.

The proposed revised bait labels for bait trays do not include any "**DIRECTIONS FOR USE**" sections, although a relatively inconspicuous sentence near the bottom of the back panels does state

"See outer box for complete Directions for Use."

This approach is inadequate. I feel that these products' bait trays should be required to bear text similar to that required for placepack labels for which registrants decline or are unable to present the full "**DIRECTIONS FOR USE**" text there. Adapted for bait trays, that text would read

"**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually."

This language directs the user appropriately to the product's full labeling and offers information which might discourage certain retailers from opening outer boxes and selling bait trays individually. Such practices are common for placepack products. Selling d-Con's trays individually would be illegal because an incompletely-labeled pesticide is misbranded. [Note especially FIFRA §2(q)(1)(F).]

Because d-Con's bait trays hold less than the 4 oz of anticoagulant bait normally required for a single placement made to control commensal rats and because the box contains significantly less bait than the 16 oz normally required for one placement at the maximum rate, the labeling for these products must include qualifying statements which

inform users that the amounts of bait provided may only be sufficient to kill limited numbers of rats. While we have tried to prohibit sale of containers of less than 4 oz of anticoagulant bait from being sold under labeling which includes claims for control of commensal rats, we have accepted directions which prescribe use of single 3-oz placepacks at loci where rats are to be baited. As a qualifier for 3-oz bait trays, we could borrow the "1-2 rats" claim permitted for 4-oz placepacks, but it would not be necessary to attach a claim to the label of a 3-oz bait tray as long as trays always were sold in multiples. The statement that we have required for 12-oz containers of anticoagulant baits claimed to control commensal rats, as modified for a package of four 3-oz bait trays, would be

> "The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats."

Registrants who seek to dispute the requiring of such statements tend to argue in terms of how many rat LD_{50} values would be expected to be in a specified quantity of bait, but such arguments fail on several grounds: (1) by definition, the LD_{50} dosage only is expected to kill half of the animals exposed to it; (2) if a toxicity figure were to be used, the LC_{99} might be a better number; (3) rats generally feed normally for the first 3-4 days of exposure to anticoagulant baits, thus tending to consume many times over the amount needed to kill them; and (4) resident rats are likely to hoard bait if possible and may inhibit access by conspecifics to palatable food sources. The determination of qualification statements is based more on the behavior of rats than it is on the toxicity of the particular anticoagulant at issue to the target species. Three ounces of bait might feed one rat for three days, two rats for one or more days, etc. So that users do not underbait the infestations that they are intending to control, I feel that the ranges presented in the qualifying statements should be on the conservative side.

Because Reckitt & Colman is up against the 3/16/96 deadline, I have structured the labeling comments under "CONCLUSIONS" in an imperative tone. This approach would permit the product manager to accept the labels "with COMMENTS", should he choose to do so, with the company then being required to make all the changes indicated. The benefits that the company would receive from this approach would be to have labels consistent with PR Notice 94-7 accepted and to know exactly what text must go on final printed labels. The disadvantage would be a loss of flexibility in label text, but label revisions could be proposed at a later date. The most important thing would

seem to be for Reckitt & Colman to have accepted labels so that they can ship these product after 3/16/96. With this in mind, I have drafted new use directions, modified in organization and content to clearly be consistent with what PR Notice 94-7 stipulates, what we have required of other rodenticide registrants, and the special needs for these bait-tray products. The directions, presented under "CONCLUSIONS" for each product as item #1., have been adapted largely from those accepted for 3282-4 on 9/18/92, with some adjustments related to items which are consistent with site claims that have been accepted for Brodifacoum baits and with some of the special text that the company desires for 3282-66 and 3282-81.

202.0 CONCLUSIONS

3282-66

Modify the proposed revised labeling submitted for this product on November 8, 1996, to read as indicated below.

1. On the back panel of the label for the 12-oz outer box, organize the heading and subheadings in the **"DIRECTIONS FOR USE"** in the manner indicated below (and in PR Notice 94-7) and modify this entire section to read as shown below. Note that some of the text in the **"USE RESTRICTIONS"**, **"SELECTION OF TREATMENT AREAS"**, and **"APPLICATION DIRECTIONS"** sections must be changed.

"DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must

be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Pellets Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT"**).

APPLICATION DIRECTIONS:

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested

areas. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

For Rats and Mice: Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when labels are printed. Do not include any graphics with these directions.

2. On the front panel of the box label, replace

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days"

with

"Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

Make this same substitution on the left side panel of the box label.

3. Delete from the back panel of the box label the sentence

> "d-CON Pellets Generation II can kill in one feeding when used as directed."

4. As written, the claim, on the left side panel of the box, which reads

> "SOLVING AMERICA'S RODENT PROBLEMS FOR OVER 40 YEARS"

is false and misleading. This product has not been registered for 40 years. What seems to be true is that d-CON baits have been used to control commensal rodents for more than 40 years. Therefore, an acceptable claim would be

> "d-CON BAITS: KILLING RATS AND MICE IN AMERICA FOR MORE THAN 40 YEARS".

5. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim to read

> "Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

As these trays are not to be sold individually, we question the need for this claim on the label for the bait trays.

6. On the back panel of the label for the bait tray, replace

> "See outer box for complete Directions for Use."

with the text shown immediately below.

> **"DIRECTIONS FOR USE**
>
> It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually."

Note that bait trays sold individually would be misbranded because they would lack complete **"DIRECTIONS FOR USE"** and **"STORAGE AND DISPOSAL"** text. As the 3-oz contents are below the minimum requirement for a single

placement of "loose" anticoagulant bait used to control commensal rats, an individually-sold container of that amount could not bear claims for controlling Norway rats or roof rats.

When setting up labels for printing, make sure that logos and other not-required items do not obscure or detract from required label statements.

3282-81

Modify the proposed revised labeling that you submitted for this product on November 11, 1995, as indicated below.

1. On the labels for the 12-oz and 3-lb outer containers, organize the heading and subheadings in the **"DIRECTIONS FOR USE"** in the manner indicated below (and in PR Notice 94-7) and modify this entire section to read as shown below. Note that some of the text in the **"USE RESTRICTIONS"**, **"SELECTION OF TREATMENT AREAS"**, and **"APPLICATION DIRECTIONS"** sections must be changed.

"DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to

hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see "**IMPORTANT**").

APPLICATION DIRECTIONS:

[The paragraph immediately below applies to the 12-oz box but not to the 3-lb box.]

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

For Rats and Mice: Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when labels are printed. Do not include any graphics with these directions.

2. On the front panels of the outer box labels, replace

"CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days"

with

"Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

Make this same substitution on the left side panel of the 12-oz box label and from wherever else it might appear on the labels for all outer packaging used for this product.

3. Delete from the front panels of the outer box labels the claim "flavor attractive to mice and rats". From the

data that have been submitted to us and linked to this product (MRID Nos. 413082-01 and 415247-01), it does not appear that this bait is very attractive to CD Strain Norway rats, at least. Data submitted subsequently (MRID No. 416037-01) suggested better acceptance by Wistar strain rats, but we were unable at the time that the submission was reviewed to establish a link between the bait used and the 3282-81 product. Consequently, we have not accepted that study for 3282-81, and the rat claims for this product technically are not supported (see our letter of October 30, 1990). Until this matter is resolved, claims to the effect that the 3282-81 product is especially attractive to target rodents are not acceptable.

4. Delete from the back panel of the 12-oz box label (and from wherever it might appear on the 3-lb box) the sentence

> "d-CON Pellets Generation II can kill in one feeding when used as directed."

5. As written, the claim, on the box labels, which reads

> "SOLVING AMERICA'S RODENT PROBLEMS FOR OVER 40 YEARS"

is false and misleading. This product has not been registered for 40 years. What seems to be true is that d-CON baits have been used to control commensal rodents for more than 40 years. Therefore, an acceptable claim would be

> "d-CON BAITS: KILLING RATS AND MICE IN AMERICA FOR MORE THAN 40 YEARS".

6. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim to read

> "Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

As these trays are not to be sold individually, we question the need for this claim on the label for the bait trays.

6. On the back panel of the label for the bait tray, replace

"See outer box for complete Directions for Use."

with the text shown immediately below.

"**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually."

Note that bait trays sold individually would be misbranded because they would lack complete "**DIRECTIONS FOR USE**" and "**STORAGE AND DISPOSAL**" text. As the 3-oz contents are below the minimum requirement for a single placement of "loose" anticoagulant bait used to control commensal rats, an individually-sold container of that amount could not bear claims for controlling Norway rats or roof rats.

When setting up labels for printing, make sure that logos and other not-required items do not obscure or detract from required label statements.

[NOTE TO PM: The labels submitted for all of these product use their current "ENVIRONMENTAL HAZARDS" text rather than the new text prescribed by PR Notices 93-3 and 93-8 (and incorporated into the format label included in PR Notice 94-7). As this review concentrates on use directions and efficacy-related claims, other portions of the labels should be checked for appropriateness. Note the "tamper-resistant bait boxes" text on the tray labels. I feel that it might be better to leave it there than to have it removed.]

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
January 30, 1996

DP BARCODE: D221493

CASE: 027444 DATA PACKAGE RECORD DATE: 12/06/95
SUBMISSION: S497519 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 356 LABEL IMPRV PROG-NOTIFI
RANKING : 0 POINTS ()
CHEMICALS: 112701 Brodifacoum 00.0050%

ID#: 003282-00081 D-CON READY MIXED GENERATION II
COMPANY: 003282 RECKITT & COLMAN INC, HOUSEHOLD PRODUCTS DIVISION
PRODUCT MANAGER: 14 ROBERT FORREST 703-305-6600 ROOM: CM2 219
PM TEAM REVIEWER: DANIEL PEACOCK 703-305-5407 ROOM: CM2 221
RECEIVED DATE: 11/09/95 DUE OUT DATE: 02/27/96

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 221493 EXPEDITE: N DATE SENT: 12/06/95 DATE RET.: / /
CHEMICAL: 112701 Brodifacoum
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 02/14/96
DIV : RD	/ /	/ /	NEGOT DATE: / /
BRAN: IRB	/ /	/ /	PROJ DATE: / /
SECT: PMT-14	/ /	/ /	
REVR :	12/6/95	1/30/96 RL	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Bill,

Please review labeling per PR Notice 94-7.

Thanks,

Dan

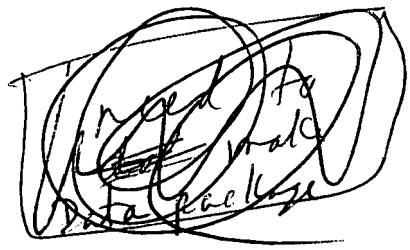
* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
128	IRB/PMT-14	12/05/95	02/13/96	Y	N	Y

11-13-95
Appl # 180182



FRONT END PROCESSING APPLICATION INFORMATION CHECK

PM 14

EPA COMPANY NUMBER 3282-81

EPA REGISTRATION NUMBER STATUS (For Amendments)

Active ✓ Cancelled _____

Not in REFS _____

"ME-TOO" CITED PRODUCT STATUS

Active _____ Cancelled _____

Not in REFS _____

PRAT RECORD CREATED _____

AMENDMENT

Opp # 180182

APPLICATION FOR AMENDMENT

	WITH DATA		NO DATA		
	INIT	DATE		INIT	DATE
FEU			FEU	[illegible]	11-13-95
SIG (DATA)			PM 14		
PM					

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

11/13/95

RUTH TRAGER
RECKITT & COLMAN INC, HOUSEHOLD PRODUCTS DIVISION
225 SUMMITT AVE
MONTVALE NJ 07645

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

PRODUCT NAME: D-CON READY MIXED GENERATION II
COMPANY NAME: RECKITT & COLMAN INC, HOUSEHOL
OPP IDENTIFICATION NUMBER: 180182
EPA REGISTRATION NUMBER: 3282-81
EPA RECEIPT DATE: 11/09/95

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Rob Forrest, Product Manager 14, at (703)-305-6600.

Sincerely,

L. Price

Front End Processing Staff
Information Services Branch
Program Management and Support Division

Recycled/Recyclable • Printed with Vegetable Oil Based Inks on 100% Recycled Paper (40% Postconsumer)

A

B

RECKITT & COLMAN

November 8, 1995

Mr. Robert Forrest (PM-14)
Insecticide / Rodenticide Branch
Registration Division, H7505C
U.S. Environmental Protection Agency
Crystal Mall, Building #2, Room 219
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: **d-CON Ready Mixed Generation II**
EPA Reg. No. 3282-81
Amendment to revise label as per PR Notice 94-7

Dear Mr. Forrest:

Enclosed are 5 copies of a draft label for d-CON Pellets Generatio II, EPA Reg. No. 3282-65. The label has been revised to include the prescribed language as per PR Notice 94-7, the change in company name from "The d-CON Company Inc." to "Household Products Division, Reckitt & Colman Inc." and label language that has been added as part of notifications.

In support of this amendment, we are submitting the following:

1) EPA Form 8570-1, Application for Pesticide Amendment, OPP Identifier No. 180182;

2) Five (5) copies of the draft label incorporating the changes listed above.

Thank you for your attention to this submission. We look forward to a favorable response as quickly as possible.

If you have any questions, you can contact me at 1-800-526-0321, ext. 5792.

Sincerely,

Ruth Trager

Ruth Trager
Senior Regulatory Affairs Associate

RECKITT & COLMAN INC.
225 Summit Avenue, Montvale, NJ 07645-1575 201-573-5700

D-221428 B

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number: 180182

Section I

1. Company/Product Number: 3282-81
2. EPA Product Manager: Robert A. Forrest
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): d-CON Ready Mixed Generation II
   PM#: 14
5. Name and Address of Applicant *(Include ZIP Code)*:
   Household Products Division
   Reckitt & Colman Inc.
   225 Summit Avenue
   Montvale, NJ 07645
   ☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No. _____
   Product Name _____

Section II

☒ Amendment - Explain below
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

AMENDMENT - Addition of the prescribed language as per PR Notice 94-7, change in company name and all notifications.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☒ Paper ☐ Other (Specify) _____
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: ☒ Label ☐ Container
4. Size(s) of Retail Container: 12 oz, 3 lbs.
5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: ☐ Lithograph ☐ Paper glued ☒ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Ruth Trager	Sr. Regulatory Affairs Associate	201-573-5792

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Ruth Trager	Sr. Regulatory Affairs Associate	
4. Typed Name: Ruth Trager	5. Date: November 8, 1995	

EPA Form 8570-1 (Rev. 12-90) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Specify the net contents of all retail containers for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

ATTACHED NOTIFICATION

TO: PM file Room

14

FROM: REG. SUPPORT BR.

match-14

NO NEW LABEL ✓

EPA REG. NO. 3282-81

NEW LABEL ATTACHED ____

COMPANY NAME ____

NEW CSF ATTACHED ____

****

____ THIS IS AN ADDITIONAL BRAND NAME

____ THIS IS A CSF PERMITTED UNDER PR NOTICE 88-6

✓ THIS IS A LABEL CHANGE PERMITTED UNDER PR NOTICE 88-6

****

✓ THIS WAS SENT TO SIG FOR CODING AND/OR MICROFICHING

✓ FILE IN JACKET

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

[ ] Registration
[ ] Amendment
[xx] Other (~~Notification~~)

OPP Identifier Number: 169913

Section I

1. Company/Product Number: 3282-81
2. EPA Product Manager: Robert Forest
3. Proposed Classification: [xx] None [ ] Restricted
4. Company/Product (Name): d-CON Ready Mixed Generation II
   PM#: 14
5. Name and Address of Applicant *(Include ZIP Code)*:
   The d-CON Company, Inc.
   225 Summit Avenue
   Montvale, NJ 07645
   [ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No._____
   Product Name_____

Section II

[ ] Amendment - Explain below
[ ] Resubmission in response to Agency letter dated_____.
[x] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated_____
[ ] "Me Too" Application.
[ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION

1 - Delete: "See Bottom of Box" from side panel (Refers to EPA Est. No. Site)

2 - Reiteration of "*Rats and Mice Will Die Within 4 or 5 Days" on side panel (NOTE: CAN KILL IN ONE FEEDING*" is currently on EPA stamped label (side panel) and will precede this statement.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)_____
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) of Retail Container
5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Paul J. Kruger	Manager EPA Regulatory Compliance	

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Paul J. Kruger	Manager EPA Regulatory Compliance	
4. Typed Name: Paul J. Kruger	5. Date: October 10, 1991	

EPA Form 8570-1 (Rev. 12-90) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

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2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
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6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

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2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
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1-5. Self-explanatory.
6. EPA Use Only.

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

October 10, 1991

Mr. Robert Forest (PM-14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall Building #2, Room 211
Arlington, VA 22202

RE: d-CON Ready Mixed Generation II
EPA Reg. No. 3282-81
Label Modification Notification

Dear Mr. Forest:

This is to notify you of two minor label modifications to our d-CON Ready Mixed Generation II (EPA Reg. No. 3282-81). These are as follows:

1 - Delete **"See Bottom of Box"** from side panel (Refers to EPA Est No. site)

2 - Reiteration of ***"Rats and Mice Will Die Within 4 or 5 Days"** on side panel. **(NOTE: "CAN KILL IN ONE FEEDING*")** is currently on EPA stamped label (side panel) and will precede this statement.

3 - In support of the above, enclosed is EPA Form 8570-1, **Application for Pesticide** (Notification), OPP Identifier No. 169913. Kindly note this change in our file.

Thank you for your cooperation.

Sincerely,

Paul Kruger

Paul Kruger
Manager, EPA Regulatory Compliance

PK /cjc

/encl

JUL 09 1991

S392205 345/38

S392206 345/38

S392207 345/38

The d-Con Company Inc.
225 Summit Ave.
Montvale, NJ 07645

392211 345/38

Gentlemen:

Subject: d-Con® Mouse Prufe II
EPA Reg. No. 3282-65
d-Con® Pellets Generation II
EPA Reg. No. 3282-66
d-Con® Lim-N8 Rat Killer in Ready to Use Bait Packs
EPA Reg. No. 3282-74
d-Con® Ready Mixed Generation II
EPA Reg. No. 3282-81
Your letter of February 22, 1991

Your request to expand the certified limits of your active ingredient (Confidential Statements of Formula dated 2/7/91) beyond the standard ones of 40 CFR 158.175(b)(2) will be acceptable, provided that you support the expansion by submission of five or more representative samples, including the raw analytical data, as required by PR Notice 91-2 and 40 CFR 158.175(b)(4).

Your two analytical methods (MRID No. 419150-01 and -02) for the determination of water in these products are acceptable.

Sincerely,

Robert A. Forest
Product Manager 14
Insecticide-Rodenticide Branch
Registration Division (H-7504C)

RAF:dbp:CM2:RM265:557-4407:7/8/91:Peacock Disk 55(8)

JUL 09 1991

The d-Con Company Inc.
225 Summit Ave.
Montvale, NJ 07645

Gentlemen:

Subject: d-Con® Mouse Prufe II
EPA Reg. No. 3282-65
d-Con® Pellets Generation II
EPA Reg. No. 3282-66
d-Con® Lim-N8 Rat Killer in Ready to Use
Bait Packs
EPA Reg. No. 3282-74
d-Con® Ready Mixed Generation II
EPA Reg. No. 3282-81
Your letter of February 22, 1991

Your request to expand the certified limits of your active ingredient (Confidential Statements of Formula dated 2/7/91) beyond the standard ones of 40 CFR 158.175(b)(2) will be acceptable, provided that you support the expansion by submission of five or more representative samples, including the raw analytical data, as required by PR Notice 91-2 and 40 CFR 158.175(b)(4).

Your two analytical methods (MRID No. 419150-01 and -02) for the determination of water in these products are acceptable.

Sincerely,

Robert A. Forest
Product Manager 14
Insecticide-Rodenticide Branch
Registration Division (H-7504C)

RAF:dbp:CM2:RM265:557-4407:7/8/91:Peacock Disk 55(8)

EXPEDITE

DATE: 7/1/91 PRODUCT CHEMIST/REVIEWER: MICHAEL J. CLIFFORD

PAGE: 1 OF 1 CONCURRED BY: Anna Skapars for Bipin Gandhi 7-1-91

COMPANY: THE d-CON COMPANY, INC. EPA REG. NO: 3282-81

PRODUCT NAME: d-CON READY MIXED GENERATION II

TO PM NO: 14 ACTION CODE: 345

BACKGROUND: Revised CSF to expand upper and lower certified limits; analytical methods for the determination of water in the formulation.

ACTIVE INGREDIENT LABEL CLAIM/ LATEST LABEL CLAIM (DATED / /)

BRODIFACOUM: 3-[3-(4'-BROMO-[1,1'-BIPHENYL]-4-YL)-1,2,3,4-TETRAHYDRO-1-NAPHTHALENYL]-4-HYDROXY-2H-1-BENZOPYRAN-2-ONE (0.005%)

REFERENCES USED: 10182-38

FOOD USE ( ) INERTS CLEARED C( ), D( ) NON FOOD USE (X)
CFR 21 PARTS 170-199 ( ) TOXIC INERTS LIST 1( ), 2( )

COMMENTS:

a) In reference to CSF dated 2/7/91 for the basic formulation, the expanding of the upper and lower certified limits of BRODIFACOUM to 65 PPM and 40 PPM, respectively is acceptable. However, since these certified limits do not conform to the standard certified limits of 40 CFR 158.175(b)(2), you will be required to submit sample analyses of five or more representative samples including the raw analytical data to support the nominal label claim as required in PR NOTICE 91-2.

b) Either one of the two analytical methods for the determination of water in the d-CON RODENTICIDE formulation would be acceptable. [redacted]

Michael J. Clifford 7/1/91

Expedite to be requested

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

DP BARCODE: D165287

CASE: 027444 DATA PACKAGE RECORD DATE: 06/18/91
SUBMISSION: S392211 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 345 TECH-FORMULA CHANGE AMND
CHEMICALS: 112701 Brodifacoum 00.0050%

ID#: 003282-00081 D-CON READY MIXED GENERATION II
COMPANY: 003282 D-CON COMPANY INC
PRODUCT MANAGER: 14 ROBERT FORREST 703-557-2600 ROOM: CM2 211
PM TEAM REVIEWER: DANIEL PEACOCK 703-557-4407 ROOM: CM2 265
RECEIVED DATE: 02/27/91 DUE OUT DATE: 05/28/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 165287 EXPEDITE: Y DATE SENT: 06/18/91 DATE RET.: / /
CHEMICAL: 112701 Brodifacoum
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 08/02/91 CSF: Y LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: RSB	/ /	/ /
SECT: PCRS	/ /	/ /
REVR : M. CLIFFORD	6/27/91	7/1/91
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

See instructions for 3282-65.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

February 22, 1991

Ms. Marilyn Mautz, (Acting PM-16)
Insecticide - Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall, Building #2, Room 211
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Reference: Amended CFS's
3282-65, d-Con® Mouse Prufe II
3282-66, d-Con® Pellets Generation II
3282-81, d-Con® Ready Mixed Generation II
3282-74, d-Con® Lim-N8 Rat Killer in Ready to Use Bait Packs

Dear Ms. Mautz:

In 1990, d-Con® fully converted from Warfarin based rodenticide baits to baits containing only brodifacoum as the active ingredient. Based on the information that we have recently obtained from analyses of production samples, we find that we are not always able to hit the brodifacoum concentrate targeted by our current Confidential Statement of Formula (CSF). The label claim and the lower limit on the CSF's is 0.005% or 50 ppm brodifacoum. [redacted]

We have considered increasing the amount of brodifacoum concentrate used in the production of the baits. However, we feel that this could significantly alter the toxicological profile of our product. We have and are currently making modifications to the production process to ensure the most uniform mixing of our bait formulations. However, our production people indicate that it is virtually impossible to guarantee that all our baits will hit the concentration of 50 ppm. I'm sure the Agency can appreciate the difficulty in producing a uniform mix at concentrations in the "ppm" range.

John Domanski recently discussed this issue with Dan Peacock and Bill Jacobs. They suggested that we amend our CSF's to cover the range of concentration for brodifacoum based on our actual manufacturing experience. [redacted]

Manufacturing process information may be entitled to confidential treatment

Another issue that must be addressed is the way we calculate the concentration of brodifacoum in the final formulation.

[redacted] I have enclosed copies of two procedures that can be used to determine the moisture content of d-Con rodenticide products.

We hope that the Agency will accept our proposals for amending our CSF's and agree with our proposal to standardize the analysis results by the correction of product moisture.

If you require additional information, or wish to discuss this matter further, please feel free to give me a call at (201)573-5329.

Sincerely,

Paul J. Kruger, Manager
EPA Regulatory Compliance

PJK:RF
Enclosures

cc: J. Domanski
W. Jacobs
D. Peacock

Manufacturing process information may be entitled to confidential treatment

ATTACHED NOTIFICATION

TO: PM Cb Noon

FROM: 14 REG. SUPPORT BR.

EPA REG. NO. 3282-81 ~~32 81 81~~

COMPANY NAME _____

NO NEW LABEL _____

NEW LABEL ATTACHED ___/___

NEW CSF ATTACHED ___/___

****

_____ THIS IS AN ADDITIONAL BRAND NAME

___/___ THIS IS A CSF PERMITTED UNDER PR NOTICE 88-6

_____ THIS IS A LABEL CHANGE PERMITTED UNDER PR NOTICE 88-6

****

_____ THIS WAS SENT TO SIG FOR CODING AND/OR MICROFICHING

___/___ FILE IN JACKET

Inert ingredient information may be entitled to confidential treatment

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 6-30-90.

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EPA **Application for Pesticide:** X NOTIFICATION [redacted]

OPP Identifier Number: 149966

Section I

1. Company/Product Number	2. Date	3. Product Manager	4. Proposed Classification
3282-81	6/14/91	Robert Forest (PM-14)	[X] General [ ] Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

The d-CON Company, Inc.
225 Summit Avenue
Montvale, NJ 07645

[ ] Check if this is a new address

6. Product Name
d-CON® Ready Mixed Generation II

Section II - Amendment Information

1. Subject
[ ] Resubmission in response to Agency letter [ ] Final printed label in response to Agency letter [X] Other *(explain below)*

Date of Letter

NOTIFICATION

Alternate supplier source of: [redacted]

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging	Unit Packaging	Water-Soluble Packaging
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No
	If "Yes," Unit package wgt / No. per container	If "Yes," Package weight / No. per container

2. Type of Container
[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other *(Specify)*

3. Location of Net Contents Information
[ ] Label [ ] Container

4. Size(s) of Retail Container

5. Location of Label Directions
[ ] On Label
[ ] On material accompanying product

6. Manner in Which Label Is Affixed To Product
[ ] Lithograph [ ] Other *(Specify)*
[ ] Paper glued
[ ] Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application).*

Name
Paul J. Kruger

Title
Manager, EPA Regulatory Compliance

Telephone No. *(Include Area Code)*
201-573-5329

6. Date Application Received *(Stamped)*

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature
Paul J. Kruger

3. Title
Manager, EPA Regulatory Compliance

4. Typed Name
Paul J. Kruger

5. Date Signed
6/14/91

EPA Form 8570-1 (Rev. 4-88) Previous editions are obsolete.

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. **Offer to Pay Statement (EPA Form 8570-27, -28, -29). (If not exempted by 40 CFR 162.9-1(b).)**
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A , for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

   An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

1-5. Self-explanatory.

6. EPA Use Only.

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

June 14, 1991

Mr. Robert Forest (PM-14)
Antimicrobial Program Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall, Building #2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: d-CON® Ready Mixed Generation II
EPA Reg. No. 3282-81
Alternate Supplier Notification

Dear Mr. Forest:

This is to notify you that the d-CON Company is adding an additional approved supplier for the [redacted] for our d-CON Ready Mixed Generation II - EPA Reg. No. 3282-81. The identity of this supplier is:

[redacted]

Enclosed please find completed EPA Forms 8570-1 (Application for Pesticide) OPP Identifier No. 149966 and 8570-4 (Confidential Statement of Formula) indicating the addition of this alternate source. Kindly note these changes accordingly in our file.

Thank you for your prompt attention to this matter.

Sincerely,

Paul J. Kruger
Manager, EPA Regulatory Compliance

PJK:vv
attachment

manufacturer of pesticides, energine and other household products.

d-CON®
Subsidiary of Sterling Drug Inc

Inert ingredient information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

S381612

OCT 30 1990

Mr. Paul J. Kruger
The d-CON Company
225 Summit Avenue
Montvale, NJ 07645

Dear Mr. Kruger:

Subject: d-CON Ready Mixed Generation II
EPA Registration No. 3282-81
Your Letter Dated August 27, 1990

The laboratory efficacy data (MRID No. 416037-01) submitted for EPA Registration No. 3282-81 indicate that this bait was accepted well enough by Norway rats to meet the acceptance criterion for anticoagulant baits and, therefore, to warrant continuation of rat claims on the label. However, consumption data for individual rats show that 7 of the 40 animals used in the rat tests with this bait accepted it at less than 20 percent. This means that a substantial proportion of subjects showed better than a 4:1 preference for challenge diet over the 3282-81 bait. Therefore, it is likely that this bait will not be accepted well by Norway rats in all actual use situations.

These efficacy data cannot be accepted, however, unless you provide a chemical analysis for active ingredient content of the test ration. You also must identify the process used to prepare the test bait and indicate the intended proportion of each ingredient in the test bait.

We note that all test subjects received bait in the "right" position for 2 of the 3 bait exposure days. For tests of such short duration, half of the subjects of each sex should receive challenge diet on the right and bait on the left on day 1. This type of design would be more likely than that employed by MB Research Laboratories, Inc., to neutralize the effects of position biases.

61856:I:Palmateer:L16-4:KENCO:10/18/90:11/17/90:CL:VO:EK:DD

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

*U.S. GPO : 1986-159-319

If you have any questions, please contact Steve Palmateer at (703) 557-4408.

Sincerely yours,

Marilyn A. Mautz
Acting Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FAST

DP BARCODE: D155382

CASE: 027444 DATA PACKAGE RECORD DATE: 09/07/90
SUBMISSION: S381612 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: TECHNICAL - LABEL REVISION AMENDMENT - D
CHEMICAL: 112701 Brodifacoum
ID#: 003282-00081 D-CON READY MIXED GENERATION II
COMPANY: 003282 D-CON COMPANY INC
PRODUCT MANAGER: 16 WILLIAM MILLER 703-557-2600 ROOM: CM#2 211
PM TEAM REVIEWER: STEPHEN PALMATEER 703-557-4408 ROOM: CM#2 265
RECEIVED DATE: 08/29/90 DUE OUT DATE: 11/27/90

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 155382 EXPEDITE: N DATE SENT: 09/07/90 DATE RET.: / /
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 10/22/90 CSF: N LABEL: N

ASSIGNED TO	DATE IN	ASSIGNED TO	DATE IN
DIV : RD	/ /	REVR : SPALMATE	/ /
BRAN: IRB	/ /	CONTR:	/ /
SECT: PMT-16	/ /		

* * * DATA PACKAGE REVIEW INSTRUCTIONS * * *

review efficacy data mrid 416037

THERE ARE NO ADDITIONAL DATA PACKAGE RECORDS

IRB BRANCH REVIEW - TSS

Record Number(s)
S381612
D155382

IN 9/7/90 OUT 10/15/90

EFFICACY

FILE OR REG. NO. 3282-81

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 8/29/90

DATE OF SUBMISSION 8/27/90

DATE SUBMISSION ACCEPTED 9/7/90

TYPE PRODUCTS(S): I, D, H, F, N, R, X, S

DATA ACCESSION NO(S). 416037-01

PRODUCT MGR. NO. 16

PRODUCT NAME(S) D-CON READY MIXED GENERATION II

COMPANY NAME The d-Con Company, Inc.

SUBMISSION PURPOSE support rat claims

CHEMICAL & FORMULATION 0.005% Brodifacoum dry bait

Efficacy Review: d-CON READY MIXED GENERATION II, 3282-81
(wp) The d-Con Company, Inc.
Montvale, NJ 07645

200.0 INTRODUCTION

200.1 Uses

A 0.005% Brodifacoum dry bait conditionally registered to control Norway rats, roof rats, and house mice "in and around homes, industrial, commercial, agricultural and public buildings."

200.2 Background Information

See efficacy reviews of reviews of 1/18/89, 5/14/90, and 7/16/90, along with other information in product jacket, which was not available for this review. Among the "conditions" placed upon this registration were the requirements that efficacy data be supplied to support rat and mouse claims. The registrant was given until 11/1/89 (9 months from 2/1/89) to supply efficacy data for these products. Prior efficacy reviews discuss past attempts to fulfill these data requirements for 3282-81. Prior efficacy tests have suggested that this product is not consistently accepted well by Norway rats.

In the efficacy review of 7/16/90, I concluded that the registrant should be given the option to reformulate the product to a formulation more acceptable to rats or to drop the rat claim from the label. As I do not have access to the product jacket, I do not know whether the PM Team, in its letter following receipt of the efficacy review of 7/16/90, gave d-Con the additional option of running a new study with the current formulation.

The current submission consists of new rat efficacy data from a study run in July of 1990 by MB Research Laboratories, Inc. of Spinnerstown, PA. The report, submitted 8/27/90, was assigned MRID number 416037-01.

201.0 DATA SUMMARY

The efficacy studies were run under the direction of Mr. Daniel R. Cerven. Tests were said to have followed EPA's Protocol 1.203. Test phase durations were modified to include 3 days of bait exposure and 10 days of post-exposure observation. These modifications of the usual 15 days of exposure and 5 days of observation often are adopted for Brodifacoum baits so that the claim "Kills rats and mice in one feeding" may be made. Rats were caged individually for the trials.

Table 1. Rat laboratory efficacy data for d-CON READY MIXED GENERATION II.

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
MB 90-9974	1	M	48.3	19.8	70.9%	1	5
	2	M	10.3	53.3	16.2%	1	5
	3	M	43.6	23.8	64.7%	1	6
	4	M	2.9	63.9	4.3%	1	4
	5	M	13.1	48.2	21.4%	1	5
	6	M	10.4	46.5	18.3%	1	7
	7	M	45.0	2.7	94.3%	1	6
	8	M	11.1	31.3	26.2%	1	6
	9	M	2.3	52.8	4.2%	1	5
	10	M	10.4	35.9	22.5%	1	5
Males	10	M	197.4	378.2	34.3%	100%	4-7
Mean					34.3%		

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
MB 90-9974	11	F	1.3	38.0	3.3%	1	6
	12	F	15.8	20.3	43.8%	1	11
	13	F	35.1	29.8	54.1%	1	8
	14	F	17.5	44.9	28.0%	1	8
	15	F	29.6	29.3	50.3%	1	7
	16	F	35.1	14.2	71.2%	1	7
	17	F	18.7	37.4	33.3%	1	9
	18	F	32.4	30.3	51.7%	1	7
	19	F	24.4	31.0	44.0%	1	7
	20	F	41.4	10.3	80.1%	1	6
Females	10	F	251.3	285.5	46.8%	100.0%	6-11
Mean					46.0%		
Both	20	B	448.7	663.7	40.3%	100.0%	4-11
Mean					40.1%		

Table 1. (Continued)

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
MB 90-9975	1	M	18.0	27.0	40.0%	1	8
	2	M	19.1	37.6	33.7%	1	6
	3	M	8.7	45.5	16.1%	1	6
	4	M	29.7	38.0	43.9%	1	7
	5	M	70.6	0.0	100.0%	1	8
	6	M	27.9	38.5	42.0%	1	6
	7	M	18.2	47.6	27.7%	1	6
	8	M	19.5	32.9	37.2%	1	6
	9	M	32.1	36.6	46.7%	1	5
	10	M	22.5	39.2	36.5%	1	4
Males	10	M	266.3	342.9	43.7%	100%	4-8
Mean					42.4%		

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
MB 90-9975	11	F	36.7	32.0	53.4%	1	6
	12	F	21.4	28.9	42.5%	1	7
	13	F	32.1	22.8	58.5%	1	5
	14	F	48.6	21.2	69.6%	1	11
	15	F	31.8	30.9	50.7%	1	11
	16	F	32.1	17.4	64.8%	1	7
	17	F	21.9	38.4	36.3%	1	5
	18	F	21.3	39.7	34.9%	1	7
	19	F	17.0	36.3	31.9%	1	9
	20	F	9.4	47.3	16.6%	1	8
Females	10	F	272.3	314.9	46.4%	100.0%	5-11
Mean					45.9%		
Both	20	B	538.6	657.8	45.0%	100.0%	4-11
Mean					44.2%		

Subjects for the tests were Wistar strain albino Norway rats from Ace Animals. Results of the laboratory efficacy trials reported are summarized in Table 1. The studies appear to have been conducted appropriately, or at least consistently with the dictates of Protocol 1.203.

Bait acceptance scores for both replicates exceeded the 33% criterion, but there were 9 animals in test MB 90-9974 that accepted bait at less than 30% of total intake (3 of these accepted bait at less than 5%). As there were several animals that also showed very high acceptance scores, it is possible that something about the set-up of the test cages caused the animals to stay with one food or the other. As the bait exposure period was for only three days and as bait was offered on the "right" to all subjects on days 1 and 3 and on the "left" only on day 2, position biases could have affected the overall acceptance scores. As rats tend to be "right-biased," the set-up could have enhanced the bait acceptance if the "right" position referred to the subject's right rather than the technician's.

The individual animals' bait acceptance scores were much better "behaved" in test MB 90-9975. Only 3 of 20 scores were below 30% and only 1 of 20 was above 70% (a 100% score).

The data from the two studies seem to be adequate to accept, but I do not know what formulation actually was tested. The study report identifies the test material by the appropriate product name, but their is no report of its composition and no chemical analysis report for the test bait included with the efficacy study.

Prior test results indicated that the crumbled-pellet formulation of 3282-81 was accepted adequately by mice but not by rats. If a different laboratory or the mixing of a new bait batch were the only changes between this test and the previous one, the increase in bait acceptance from one score of 18% and another of 28% in two prior tests to scores of 40% and 45% in the new rat tests with 3282-81 would be a bit hard to believe. In view of the poor acceptance by a number of subjects in the new tests, it is likely that this type of bait does not appeal to all rats.

202.0 CONCLUSIONS

The laboratory efficacy data submitted for 3282-81 indicate that this bait was accepted well enough by Norway rats to meet the acceptance criterion for anticoagulant baits and, therefore, to warrant continuation of rat claims on the label. However, consumption data for individual rats show that seven of the 40 animals used in the rat tests with this bait accepted in at less than 20%. This means that a

substantial proportion of subjects showed better than a 4:1 preference for challenge diet over the 3282-81 bait. Therefore, it is likely that this bait will not be accepted well by all Norway rats in all actual use situations.

These efficacy data cannot be accepted, however, unless you provide a chemical analysis for active ingredient content of the test ration. You also must identify the process used to prepare the test bait and indicate the intended proportion of each ingredient in the test bait.

We note that all test subjects received bait in the "right" position for two of the three bait exposure days. For tests of such short duration, half of the subjects of each sex should receive bait initially on the right, while the other half receive challenge diet on the right and bait on the left on day 1. This type of design would be more likely than that employed by MB Research Laboratories, Inc., to neutralize the effects of position biases.

[NOTE TO PM: If this bait has been reformulated, d-Con must submit new mouse tests. If the bait has not been reformulated, we should retain a healthy skepticism regarding the results reported in this test.]

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
October 15, 1990

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

25 SEP 1990

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338175

Mr. Paul J. Kruger
The d-CON Company
225 Summit Avenue
Montvale, NJ 07645

Dear Mr. Kruger:

Subject: d-CON Ready Mixed Generation II
EPA Registration No. 3282-81
Your Letter Dated August 27, 1990

We note in the subject letter that you state the following:

> enclosed are three copies of the following rat (Norway) efficacy data (bait acceptability) study:
>
> 1. Standard Rat Anticoagulant Dry Bait Laboratory Test Method.

This data was not enclosed. Perhaps it was enclosed with yet another copy of this letter. When you make a submission please send the submission to me and do not send eight copies to the reviewers as it greatly confuses the data screen personnel and slows down processing of the submission.

Sincerely yours,

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

61837:I:A-5:Palmateer:LM-9:KENCO:09/21/90:11/19/90:de:ejh

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

*U.S. GPO : 1985-467-853

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

August 27, 1990

Mr. William Miller (PM-16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
U. S. Environmental Protection Agency
Crystal Mall, Building #2, Room 211
1921 Jefferson Davis Highway
Arlington VA 22202

RE: **d-CON READY MIXED GENERATION II**
EPA REGISTRATION NO. 3282-81
EFFICACY DATA INFORMATION

Dear Mr. Miller:

As indicated in my July 31 letter relative to the above mentioned product, enclosed are three copies of the following rat (Norway) efficacy data (bait acceptability) study:

1. Standard Rat Anticoagulant Dry Bait Laboratory Test Method.

Please note that the results demonstrate a bait composite acceptance in excess of 42% with a resultant mortality of 100%. These data should satisfy the requirements for the rat control claims on the label.

Sincerely,

Paul J. Kruger
Manager, Technical Coordination

PJK/mmh
Enclosure

pk/memoaug./5

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

August 28, 1990

Mr. William Miller (PM-16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
U. S. Environmental Protection Agency
Crystal Mall, Building #2, Room 211
1921 Jefferson Davis Highway
Arlington VA 22202

RE: EFFICACY DATA GENERATED FOR:
d-CON® MOUSE KILLING STATION
EPA REG. NO. 3282-79

Dear Mr. Miller:

In compliance with the conditional registration of the above d-CON rodenticide, enclosed are three copies of the following efficacy report:

1. House Mouse Prebaited Bait Station Laboratory Test
   d-CON Mouse Killing Station (EPA Reg. No. 3282-79)

Thank you for you cooperation.

Sincerely,

Paul J. Kruger
Manager, Technical Coordination

RJK/mmh
Enclosure

pk/memoaug./6

manufacturer of pesticides, energine and other household products.

d-CON®
Subsidiary of Sterling Drug Inc

21 AUG 1990

S278473

268166

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Mr. Paul J. Kruger
The d-Con Company
225 Summit Avenue
Montvale, NJ 07645

Dear Mr. Kruger:

Subject: d-Con Ready Mixed Generation II
EPA Registration No. 3282-81
Your Letter Dated July 31, 1990

We are in receipt of the subject letter and note that you intend to submit repeat Norway rat efficacy data within 7 to 14 days. Be sure to submit in the format outlined in PR Notice 86-5.

If you have any questions, please contact Steve Palmateer at (703) 557-4408.

Sincerely yours,

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

61818:I:Palmateer:16-1:KENCO:8/16/90:10/16/90:EK:VO:CL

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

July 31, 1990

Mr. William Miller (PM-16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U. S. Environmental Protection Agency
Crystal Mall, Building #2, Room 211
1921 Jefferson Davis Highway
Arlington VA 22202

Subject: d-Con Ready Mixed Generation II
EPA Registration No. 3282-81
Efficacy Data Information

Dear Mr. Miller:

Thank you for your letter of July 26 in which you indicated that your overall assessment of the product performance of d-Con Ready Mixed Generation II was essentially unchanged based on the test laboratory's summary tables and the raw data sheets recently forwarded to you.

In your letter you also asked me to contact you within 15 days of receipt, advising as to how we were going to resolve the rat efficacy data (bait acceptability) problem.

As discussed with Mr. Steve Palmateer, I'm informing the Agency that we have successfully conducted a rat (Norway) bait acceptance efficacy study. The test results demonstrate a bait acceptance in excess of 40% with a resultant 100% mortality. This study has just been concluded with a final report anticipated in the next 7-14 days. Once this report is received, three copies will be promptly forwarded to your attention. This should satisfy the requirements in order to continue the rat claims on the label.

Your cooperation is appreciated. Should you have any questions, please contact me at 201/573-5329.

Sincerely,

Paul J. Kruger
Manager, Technical Coordination

cc: Mr. Steve Palmateer

RJK:mjz
dcrm.doc

26 JUL 1990

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Mr. Paul J. Kruger
The d-CON Company, Inc.
225 Summit Avenue
Montvale, NJ 07645

Dear Mr. Kruger:

Subject: d-CON Ready Mixed Generation II
EPA Registration No. 3282-81
Your Submission Dated June 13, 1990

The laboratory efficacy data (MRID No. 413082) for EPA Registration No. 3282-81 indicate that this bait is not accepted well enough by Norway rats to warrant continuation of rat claims on the label. Consumption data for individual rats show that over half of the 40 animals used in the rat tests with this bait accepted in at less than 20 percent. This means that the majority of the subjects showed better than a 4:1 preference for challenge diet over the EPA Registration No. 3282-81 bait. Therefore, it is not likely that the low acceptance scores obtained in the two tests with this bait were fluke results.

To continue registration of this product you must either delete Norway rat and roof rat claims from the product label, or amend the formulation to one that is well accepted by (and lethal to) Norway rats and house mice. The effectiveness of the new formulation would have to be documented through new laboratory efficacy studies.

We noted several instances in which entries in the test laboratory's summary tables did not correspond to the values that we obtained when we worked directly from raw data sheets. However, after appropriate corrections were made, our overall assessment of the product performance was essentially unchanged.

61801:I:Palmateer:M-11:KENCO:7/24/90:8/20/90:EK:JH:EK

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

Please inform the Agency within 15 days of receipt of this letter how you are going to resolve the rat efficacy data problem. You are reminded that a condition of this registration was the following:

b. With 9 months of the date on this Registration Notice, submit the results of an efficacy test conducted both on rats and mice. The test results must demonstrate 90 percent or better mortality and 33 percent or better acceptance in both rats and mice.

If you have any questions, please contact Steve Palmateer at (703) 557-4408.

Sincerely yours,

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

IRB BRANCH REVIEW - TSS

Record Number(s)

3282-66: 266297
3282-81: 266298

IN 6/22/90 OUT 7/16/90

EFFICACY

FILE OR REG. NO. see above

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 6/14/90

DATE OF SUBMISSION 6/13/90

DATE SUBMISSION ACCEPTED 6/22/90

TYPE PRODUCTS(S): I, D, H, F, N, R,x S

DATA ACCESSION NO(S). 3282-66: 413006-01, 415246-01; 3282-81: 413082-01, 515247-01

PRODUCT MGR. NO. -16

PRODUCT NAME(S) d-CON ~~PELLETS~~ READY MIXED GENERATION II

COMPANY NAME The d-Con Company, Inc.

SUBMISSION PURPOSE complete efficacy data submission

CHEMICAL & FORMULATION 0.005% Brodifacoum dry baits

Efficacy Review: d-CON PELLETS GENERATION II, 3282-66
d-CON READY MIXED GENERATION II, 3282-81
(wp) The d-Con Company, Inc.
Montvale, NJ 07645

200.0 INTRODUCTION

200.1 Uses

0.005% Brodifacoum dry baits conditionally registered to control Norway rats, roof rats, and house mice "in and around homes, industrial, commercial, agricultural and public buildings.

200.2 Background Information

See efficacy review of 12/29/88 for 3282-66, efficacy review of 1/18/89 for 3282-81, efficacy review of 5/14/90 for both products, and other information in product jackets. Among the "conditions" placed upon these registrations were requirements that efficacy data be supplied to support rat and mouse claims. The registrant was given until 11/1/89 (9 months from 2/1/89) to supply efficacy data for these products. Incomplete reports of laboratory efficacy studies were discussed in the efficacy review of 5/14/90.

The current submissions consist of raw data sheets and certain intermediate summary tables for the studies discussed in the efficacy review of 5/14/90. The report submitted 11/17/89 were assigned MRID numbers 413006-01 (for 3282-66) and 413082-01. The additional tables and raw data sheets for 3282-66 were assigned MRID no. 415246-01. Those for 3282-81 were assigned MRID no. 415247-01.

201.0 DATA SUMMARY

The efficacy studies were run at the College of Veterinary Medicine of Mississippi State University under the direction of Dr. James G. Miller, a long-time d-Con consultant. Tests were said to have followed EPA's Protocols 1.203 and 1.204. Test phase durations were modified to include 3 days of bait exposure and 10 days of post-exposure observation. These modifications of the usual 15 days of exposure and 5 days of observation often are adopted for Brodifacoum baits so that the claim "Kills rats and mice in one feeding" may be made. Mice were group-caged for the trials with 3282-66, but were caged individually for the trials with 3282-81. For the mouse trials with 3282-66, mice were housed in groups of ten animals (5 females, 5 males) in metal cages that were much larger than the upper limit specified in Protocol 1.204. I

do not find the cage size used to be unacceptable, however, as I believe larger cages to be an improvement on the limits set in Protocol 1.204.

Subjects for the rat tests were CD strain albino Norway rats from Charles River Laboratories and Swiss-Webster strain house mice.

Table A. Results of laboratory efficacy trials with d-Con Brodifacoum baits 3282-66 and 3282-81.

Product	Test	% Acceptance	% Mortality	Days to Death
3282-66	Rats #1	34.6%	100%	3-6
	Rats #2	42.1%	100%	3-6
	Mice #1	33.6%	95%	2-12
	Mice #2	25.7%	100%	3-8
3282-81	Rats #1	28.1%	95%	3-13?
	Rats #2	18.1%	90%	4-11
	Mice #1	41.4%	100%	3-8
	Mice #2	41.1%	95%	4-8

Results of all trials are summarized above in Table A. More detailed results are presented in Tables 1-4 at the end of this review. Tables 1-4 were generated from the "raw" data sheets by use of a Lotus spreadsheet set-up that I have developed for handling data from laboratory efficacy tests of commensal rodenticide baits. As can be seen from comparing Table A above with Table 1 from the efficacy review of 5/14/90, several summary numbers have changed somewhat (cf. "% Acceptance" data) as a result of regenerating the values from entries in the raw data sheets. The raw data sheets for bait consumption presented single values which, inspection indicated, were too large to be daily consumption results. I determined, however, that subtracting the numbers presented from 50 g and summing results for the diet across bait exposure days yielded the consumption figures presented in Dr. Miller's "TABULATION" tables for individual subjects (except for the few instances where there seemed to be mistakes in the "TABULATION TABLE"). I surmised that containers were replenished daily so that they each held 50 g of food at the start of each test day. Such a procedure is consistent with the methods prescribed in Protocol 1.203.

There were additional discrepancies in results between the "TABULATION" tables and Dr. Millers "Rodenticidal and

Organoleptic Assay" tables. The latter tables may have been generated independently from the "TABULATION" tables.

The test results indicate that the pelleted bait (3282-66) was accepted reasonably well by rats (particularly females) but not as well by mice and that the crumbled pellets (3282-81) were accepted adequately by mice but not by rats. Bait acceptance was below the criterion of 33% in both rat tests with 3282-81. In test M9204 (see Table 3), challenge diet was preferred to bait by a ratio of better than 4:1. It appears that the bait preparation in that product is not very attractive to Norway rats. Three survivors (among 40 rats exposed to 3282-81) is a relatively high proportion for a Brodifacoum laboratory test. Bait acceptance scores for these survivors were below the mean acceptances for all rats in these tests (see Table 3).

The data received for 3282-66 are adequate to support the label claims for that product. The data received for 3282-81 are adequate to support claims for control of house mice. If d-Con wishes to retain Norway rat and roof rat claims for that product, the company must reformulate the bait and show that the new preparation will pass acceptance (33%) and mortality (90%) criteria for rats and mice.

202.0 CONCLUSIONS

Comments for 3282-66

The data received for 3282-66 are adequate to support claims that this product will control commensal rats and mice, although bait acceptance by mice was below criterion in one test. No further efficacy data are required for this product at this time.

We noted several instances in which entries in the test laboratory's summary tables did not correspond to the values that we obtained when we worked directly from raw data sheets. However, after appropriate corrections were made, our overall assessment of product performance was essentially unchanged.

Comments for 3282-81

The laboratory efficacy data for 3282-81 indicate that this bait is not accepted well enough by Norway rats to warrant continuation of rat claims on the label. Consumption data for individual rats show that over half of the 40 animals used in the rat tests with this bait accepted in at less than 20%. This means that the majority of subjects showed better that a 4:1 preference for challenge diet over the 3282-81 bait. Therefore, it not likely that the low acceptance scores obtained in the two tests with this bait were fluke results.

To continue registration of this product you must either delete Norway rat and roof rat claims from the product label, or amend the formulation to one that is well accepted by (and lethal to) Norway rats and house mice. The effectiveness of the new formulation would have to be documented through new laboratory efficacy studies.

We noted several instances in which entries in the test laboratory's summary tables did not correspond to the values that we obtained when we worked directly from raw data sheets. However, after appropriate corrections were made, our overall assessment of product performance was essentially unchanged.

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
July 16, 1990

Table 1. Rat laboratory efficacy data for d-Con Pellets Generation II (3282-66).

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9210	1	M	37.3	27.0	58.0%	1	5
	2	M	19.9	40.2	33.1%	1	5
	3	M	9.9	56.0	15.0%	1	4
	4	M	5.6	66.6	7.8%	1	4
	5	M	24.1	52.2	31.6%	1	5
	6	M	8.6	65.4	11.6%	1	5
	7	M	23.4	57.2	29.0%	1	4
	8	M	25.5	42.0	37.8%	1	6
	9	M	13.2	54.9	19.4%	1	4
	10	M	14.7	63.0	18.9%	1	4
Males Mean	10	M	182.2	524.5	25.8% 26.2%	100%	4-6

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9210	1	F	21.5	18.5	53.8%	1	4
	2	F	55.9	24.7	69.4%	1	6
	3	F	36.4	26.1	58.2%	1	4
	4	F	36.6	28.6	56.1%	1	4
	5	F	15.7	42.4	27.0%	1	4
	6	F	8.0	69.9	10.3%	1	4
	7	F	19.2	36.1	34.7%	1	4
	8	F	25.4	42.2	37.6%	1	5
	9	F	40.7	21.3	65.6%	1	3
	10	F	25.8	49.8	34.1%	1	5
Females Mean	10	F	285.2	359.6	44.2% 44.7%	100.0%	3-6
Both Mean	20	B	467.4	884.1	34.6% 35.5%	100.0%	3-6

Table 1. (Continued)

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9211	1	M	21.2	52.4	28.8%	1	5
	2	M	16.7	60.0	21.8%	1	5
	3	M	30.8	43.6	41.4%	1	4
	4	M	5.8	68.8	7.8%	1	4
	5	M	32.2	42.7	43.0%	1	5
	6	M	34.5	36.7	48.5%	1	5
	7	M	23.8	45.3	34.4%	1	4
	8	M	37.2	32.4	53.4%	1	6
	9	M	18.1	45.6	28.4%	1	4
	10	M	50.4	20.2	71.4%	1	4
Males	10	M	270.7	447.7	37.7%	100%	4-6
Mean					37.9%		

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9211	1	F	47.1	9.3	83.5%	1	4
	2	F	20.4	41.3	33.1%	1	6
	3	F	26.8	26.1	50.7%	1	4
	4	F	9.6	51.0	15.8%	1	4
	5	F	44.7	30.9	59.1%	1	4
	6	F	23.4	40.7	36.5%	1	4
	7	F	12.2	51.2	19.2%	1	4
	8	F	26.9	44.3	37.8%	1	5
	9	F	26.8	20.0	57.3%	1	3
	10	F	53.0	8.6	86.0%	1	5
Females	10	F	290.9	323.4	47.4%	100.0%	3-6
Mean					47.9%		
Both	20	B	561.6	771.1	42.1%	100.0%	3-6
Mean					42.9%		

Table 2. Mouse laboratory efficacy data for d-Con Pellets Generation II (3282-66).

TEST #	BOWL PAIR	SEXES	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9208	1	5 M	15.0	53.0	22.1%	4	3-12
Group 1	2	5 F	15.4	54.7	22.0%	5	4-6
Group 1 Mean	BOTH	BOTH	30.4	107.7	22.0% 22.0%	90%	3-12
M9208	1	5 M	31.9	34.4	48.1%	5	3-5
Group 2	2	5 F	28.1	36.9	43.2%	5	2-6
Group 2 Mean	BOTH	BOTH	60.0	71.3	45.7% 45.7%	100%	2-6
M9208 Mean	ALL	BOTH	90.4	179.0	33.6% 33.8%	95%	2-12
M9209	1	5 M	24.4	49.6	33.0%	5	3-7
Group 1	2	5 F	18.8	53.2	26.1%	5	3-5
Group 1 Mean	BOTH	BOTH	43.2	102.8	29.6% 29.5%	100%	3-7
M9209	1	5 M	15.6	61.7	20.2%	5	3-6
Group 2	2	5 F	18.5	59.0	23.9%	5	5-8
Group 2 Mean	BOTH	BOTH	34.1	120.7	22.0% 22.0%	100%	3-8
M9209 Mean	ALL	BOTH	77.3	223.5	25.7% 25.8%	100%	3-8

Table 3. Rat laboratory efficacy data for d-Con Ready Mixed Generation II (3282-81).

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9201	1	M	11.6	53.8	17.7%	1	5
	2	M	4.7	54.3	8.0%	1	4
	3	M	8.4	56.9	12.9%	1	5
	4	M	9.4	60.6	13.4%	0	-
	5	M	10.6	58.7	15.3%	1	8
	6	M	34.0	26.8	55.9%	1	3
	7	M	11.9	47.3	20.1%	1	4
	8	M	10.6	51.0	17.2%	1	8
	9	M	32.0	23.8	57.3%	1	4
	10	M	19.1	40.8	31.9%	1	4
Males	10	M	152.3	474.0	24.3%	90%	3-8
Mean					25.0%		

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9201	1	F	10.6	63.1	14.4%	1	12
	2	F	11.1	42.0	20.9%	1	4
	3	F	5.6	52.1	9.7%	1	13?
	4	F	37.6	25.9	59.2%	1	5
	5	F	30.8	26.2	54.0%	1	4
	6	F	21.7	35.6	37.9%	1	4
	7	F	8.8	58.1	13.2%	1	5
	8	F	38.0	21.0	64.4%	1	6
	9	F	9.7	46.5	17.3%	1	5
	10	F	22.4	46.1	32.7%	1	5
Females	10	F	196.3	416.6	32.0%	100.0%	4-13?
Mean					32.4%		
Both	20	B	348.6	890.6	28.1%	95.0%	3-13?
Mean					28.7%		

Table 3. (Continued)

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9204	1	M	17.8	48.7	26.8%	1	6
	2	M	8.9	57.0	13.5%	1	11
	3	M	9.0	63.0	12.5%	1	6
	4	M	16.5	51.5	24.3%	1	4
	5	M	3.1	53.4	5.5%	0	-
	6	M	6.2	58.3	9.6%	1	9
	7	M	11.8	62.2	15.9%	0	-
	8	M	17.9	45.9	28.1%	1	5
	9	M	20.9	52.1	28.6%	1	5
	10	M	9.1	60.8	13.0%	1	5
Males Mean	10	M	121.2	552.9	18.0% 17.8%	80%	4-11

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9204	1	F	4.8	57.4	7.7%	1	6
	2	F	4.9	55.9	8.1%	1	9
	3	F	5.9	51.0	10.4%	1	7
	4	F	9.2	58.2	13.6%	1	4
	5	F	17.9	50.1	26.3%	1	4
	6	F	5.6	50.7	9.9%	1	7
	7	F	17.7	34.0	34.2%	1	7
	8	F	20.9	39.2	34.8%	1	6
	9	F	11.8	57.9	16.9%	1	5
	10	F	11.7	40.8	22.3%	1	6
Females Mean	10	F	110.4	495.2	18.2% 18.4%	100.0%	4-9
Both Mean	20	B	231.6	1048.1	18.1% 18.1%	90.0%	4-11

Table 4. Mouse laboratory efficacy data for d-Con Ready Mixed Generation II (3282-81).

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9202	1	M	4.3	10.3	29.5%	1	6
	2	M	6.5	15.8	29.1%	1	5
	3	M	7.4	18.2	28.9%	1	5
	4	M	6.6	14.9	30.7%	1	7
	5	M	11.7	9.3	55.7%	1	3
	6	M	13.9	5.5	71.6%	1	4
	7	M	9.1	16.0	36.3%	1	8
	8	M	15.6	12.5	55.5%	1	5
	9	M	9.0	10.0	47.4%	1	5
	10	M	4.6	14.1	24.6%	1	5
Males Mean	10	M	88.7	126.6	41.2% 40.9%	100%	3-8
TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9202	1	F	6.3	13.9	31.2%	1	5
	2	F	5.5	8.0	40.7%	1	5
	3	F	6.2	7.5	45.3%	1	5
	4	F	8.1	10.9	42.6%	1	5
	5	F	8.2	10.8	43.2%	1	5
	6	F	10.9	11.3	49.1%	1	6
	7	F	5.7	14.3	28.5%	1	4
	8	F	9.8	8.4	53.8%	1	5
	9	F	6.6	8.2	44.6%	1	4
	10	F	8.4	13.1	39.1%	1	4
Females Mean	10	F	75.7	106.4	41.6% 41.8%	100.0%	4-6
Both Mean	20	B	164.4	233.0	41.4% 41.4%	100.0%	3-8

Table 4. (Continued)

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9205	1	M	5.2	10.5	33.1%	1	5
	2	M	7.5	10.5	41.7%	1	4
	3	M	2.7	13.1	17.1%	1	6
	4	M	7.9	12.9	38.0%	1	6
	5	M	9.2	11.8	43.8%	1	6
	6	M	7.7	10.2	43.0%	1	4
	7	M	9.4	8.8	51.6%	1	4
	8	M	5.1	9.8	34.2%	1	6
	9	M	10.2	11.1	47.9%	1	6
	10	M	6.8	16.8	28.8%	1	4
Males Mean	10	M	71.7	115.5	38.3% 37.9%	100%	4-6

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
M9205	1	F	15.2	8.9	63.1%	1	6
	2	F	7.2	7.3	49.7%	1	6
	3	F	3.9	11.4	25.5%	1	6
	4	F	7.0	11.3	38.3%	1	6
	5	F	11.2	10.7	51.1%	0	-
	6	F	4.9	9.5	34.0%	1	4
	7	F	2.3	8.7	20.9%	1	8
	8	F	6.9	9.9	41.1%	1	4
	9	F	7.1	8.3	46.1%	1	6
	10	F	8.8	8.1	52.1%	1	5
Females Mean	10	F	74.5	94.1	44.2% 42.2%	90.0%	4-8
Both Mean	20	B	146.2	209.6	41.1% 40.1%	95.0%	4-8

JUN 21 1990

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

D-CON COMPANY INC.
225 SUMMIT AVENUE
NONTVALE, NJ 07645

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/14/90. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

In the transmittal document, please include a clear list or bibliography of the studies which are being submitted in the data package.

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

415247-00

June 13, 1990

Mr. William Miller (PM-16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall, Building #2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: d-CON READY MIXED GENERATION II
EPA Reg. No. 3282-81
Efficacy Data Information

Dear Mr. Miller:

As requested in your May 22nd letter regarding our submitted efficacy data (MRID #413082) attached for your review are the data tables and copies of raw data sheets (3 copies each) pertinent to the above study. These data indicates bait consumption by individual animals (rat tests) and individual test groups (mouse tests).I understand that conditional registration will continue if we provided this information within 30 days of receipt of your letter. 41524701

As the summary data submitted suggests that this bait may not be adequately accepted by rats, we are initiating a new acceptability efficacy study as outlined in your letter. These test results will be promptly forwarded to your attention when available.

Sincerely,

Paul J. Kruger
Manager, Technical Coordination

PJK/ca
enc.

d-CON®
Subsidiary of Sterling Drug Inc.

ATTACHED NOTIFICATION

TO: PM file 16

FROM: REG. SUPPORT BR.

NO NEW LABEL ✓

EPA REG. NO. 3282-81

NEW LABEL ATTACHED ____

COMPANY NAME ____

NEW CSF ATTACHED ____

****

✓ THIS IS AN ADDITIONAL BRAND NAME

____ THIS IS A CSF PERMITTED UNDER PR NOTICE 88-6

____ THIS IS A LABEL CHANGE PERMITTED UNDER PR NOTICE 88-6

****

____ THIS WAS SENT TO SIG FOR CODING AND/OR MICROFICHING

✓ FILE IN JACKET

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

April 4, 1990

Mr. William Miller (PM-16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall, Building #2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: d-Con Ready Mixed Generation II
EPA Reg. No. 3282-81
Alternate Name Notification

Dear Mr. Miller:

This is to inform you of an alternate name for our d-Con Ready Mixed Generation II (EPA Reg. No. 3282-81). The alternate name is as follows:

d-Con Ready Mixed Baitbits

Enclosed please find completed EPA form 8570-1 (OPP Identifier Number 139070 - Application for Pesticide Amendment, indicating the addition of this alternate name. Kindly note these changes accordingly in our file. Thank you for your prompt attention to this matter.

Sincerely,

Ruth Trager

Ruth Trager
Technical Support Specialist

RT/ca

Please read instructions and notice on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 6-30-90.

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EPA

Application for Pesticide: [ ] Registration [xx] Amendment

OPP Identifier Number: 139070

Section I

1. Company/Product Number	2. Date	3. Product Manager	4. Proposed Classification
3282-81	4/4/90	W. Miller (PM-16)	[xx] General [ ] Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

d-Con Company, Inc.
225 Summit Avenue
Montvale, NJ 07645

[ ] Check if this is a new address

6. Product Name

d-Con Ready Mixed Generation II

Section II - Amendment Information

1. Subject

[ ] Resubmission in response to Agency letter
[ ] Final printed label in response to Agency letter
[xx] Other *(explain below)*

Date of Letter

NOTIFICATION

Alternate name of:

d-Con Ready Mixed Baitbits

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging	Unit Packaging	Water-Soluble Packaging
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No
	If "Yes," Unit package wgt / No. per container	If "Yes," Package weight / No. per container

2. Type of Container: [ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other *(Specify)*

3. Location of Net Contents Information: [ ] Label [ ] Container

4. Size(s) of Retail Container

5. Location of Label Directions: [ ] On Label [ ] On material accompanying product

6. Manner in Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other *(Specify)*

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application).*

Name: Ruth Trager

Title: Technical Support Specialist

Telephone No. *(Include Area Code)*: 201-573-5328

6. Date Application Received *(Stamped)*

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Ruth Trager

3. Title: Technical Support Specialist

4. Typed Name: Ruth Trager

5. Date Signed: 4/4/90

EPA Form 8570-1 (Rev. 9-88) Previous editions are obsolete.

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

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1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

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Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

   An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

1-5. Self-explanatory.

6. EPA Use Only.

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United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EPA

Application for Pesticide: [ ] Registration [XX] Amendment

OPP Identifier Number: 139070

Section I

1. Company/Product Number	2. Date	3. Product Manager	4. Proposed Classification
3282-81	4/4/90	W. Miller (PM-16)	[XX] General [ ] Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

d-Con Company, Inc.
225 Summit Avenue
Montvale, NJ 07645

[ ] Check if this is a new address

6. Product Name

d-Con Ready Mixed Generation II

Section II - Amendment Information

1. Subject

[ ] Resubmission in response to Agency letter [ ] Final printed label in response to Agency letter [XX] Other *(explain below)*

Date of Letter

NOTIFICATION

Alternate name of:

d-Con Ready Mixed Baitbits

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging	Unit Packaging	Water-Soluble Packaging
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No
	If "Yes," Unit package wgt / No. per container	If "Yes," Package weight / No. per container

2. Type of Container

[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other *(Specify)*

3. Location of Net Contents Information

[ ] Label [ ] Container

4. Size(s) of Retail Container

5. Location of Label Directions

[ ] On Label
[ ] On material accompanying product

6. Manner in Which Label Is Affixed To Product

[ ] Lithograph [ ] Other *(Specify)*
[ ] Paper glued
[ ] Stenciled

Section IV

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Name: Ruth Trager

Title: Technical Support Specialist

Telephone No. *(Include Area Code)*: 201-573-5328

6. Date Application Received *(Stamped)*

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Ruth Trager

3. Title: Technical Support Specialist

4. Typed Name: Ruth Trager

5. Date Signed: 4/4/90

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1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

   An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

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1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

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United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EPA

Application for Pesticide: [ ] Registration [XX] Amendment

OPP Identifier Number: 139070

Section I

1. Company/Product Number	2. Date	3. Product Manager	4. Proposed Classification
3282-81	4/4/90	W. Miller (PM-16)	[XX] General [ ] Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

d-Con Company, Inc.
225 Summit Avenue
Montvale, NJ 07645

[ ] Check if this is a new address

6. Product Name

d-Con Ready Mixed Generation II

Section II - Amendment Information

1. Subject

[ ] Resubmission in response to Agency letter [ ] Final printed label in response to Agency letter [XX] Other *(explain below)*

Date of Letter

NOTIFICATION

Alternate name of:

d-Con Ready Mixed Baitbits

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging	Unit Packaging	Water-Soluble Packaging
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No
	If "Yes," Unit package wgt / No. per container	If "Yes," Package weight / No. per container

2. Type of Container

[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other *(Specify)*

3. Location of Net Contents Information

[ ] Label [ ] Container

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[ ] On Label
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Contact Point

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United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EPA

Application for Pesticide: [ ] Registration [X] Amendment

OPP Identifier Number: 139070

Section I

1. Company/Product Number	2. Date	3. Product Manager	4. Proposed Classification
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5. Name and Address of Applicant *(Include ZIP Code)*

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225 Summit Avenue
Montvale, NJ 07645

[ ] Check if this is a new address

6. Product Name: d-Con Ready Mixed Generation II

Section II - Amendment Information

1. Subject
[ ] Resubmission in response to Agency letter [ ] Final printed label in response to Agency letter [X] Other *(explain below)*

Date of Letter:

NOTIFICATION

Alternate name of:

d-Con Ready Mixed Baitbits

Section III

1. Material This Product Will Be Packaged In

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[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No
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2. Type of Container: [ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other *(Specify)*

3. Location of Net Contents Information: [ ] Label [ ] Container

4. Size(s) of Retail Container

5. Location of Label Directions: [ ] On Label [ ] On material accompanying product

6. Manner in Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other *(Specify)*

Section IV

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Title: Technical Support Specialist

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1-5. Self-explanatory.

6. EPA Use Only.

22 MAY 1990

310
13

252/122

Dr. John J. Domanski
The d-CON Company INC
225 Summit Avenue
Montvale, NJ 07645

Dear Dr. Domanski

Subject: d-CON READY MIXED GENERATION II
EPA Reg. No. 3282-81
Your submission Dated November 17, 1989

We have reviewed the data (MRID 413082) enclosed with subject submission and have the following comments:

1. Review of the efficacy data submitted for this product cannot be completed until data tables and copies of raw data sheets are submitted which show bait consumption by individual animals. Conditional registration will continue if this information is provided within 30 days of the date of this letter.

2. The summary data submitted suggest that this bait would not perform well enough against Norway rats to warrant continuation of rat claims on the label. Therefore, you must submit new efficacy data which show that the current formulation is adequately accepted (33%) by rats, delete rat claims from the product label, or amend the formulation to one that is well accepted by (and lethal to) Norway rats. The effectiveness of the new formulation would have to be documented through laboratory efficacy studies.

Sincerely yours,

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

59274:I:Palmateer:M-13:KENCO:5/17/90:7/17/90:dg:SW:VO:EK:CL

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

IRB BRANCH REVIEW - TSS

Record Number(s)
3282-66: 256126
3282-81: 256127

IN: 3/14/90 OUT 5/14/90

EFFICACY

FILE OR REG. NO. as above

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 11/20/89

DATE OF SUBMISSION 11/17/89

DATE SUBMISSION ACCEPTED 3/14/90

TYPE PRODUCTS(S): I, D, H, F, N, R&S

DATA ACCESSION NO(S). 3282-66: 413006-01 3282-81: 413082-01

PRODUCT MGR. NO. 16

PRODUCT NAME(S) d-CON [redacted] READY MIXED GENERATION II

COMPANY NAME The d-Con Company, Inc.

SUBMISSION PURPOSE support label claims

CHEMICAL & FORMULATION 0.005% Brodifacoum dry baits

Efficacy Review: d-CON PELLETS GENERATION II, 3282-66
d-CON READY MIXED GENERATION II, 3282-81
(wp) The d-Con Company, Inc.
Montvale, NJ 07645

200.0 INTRODUCTION

200.1 Uses

0.005% Brodifacoum dry baits conditionally registered to control Norway rats, roof rats, and house mice "in and around homes, industrial, commercial, agricultural and public buildings.

200.2 Background Information

See efficacy review of 12/29/88 for 3282-66 and efficacy review of 1/18/89 for 3282-81, along with other information in product jackets. Among the "conditions" placed upon these registrations were requirements that efficacy data be supplied to support rat and mouse claims. The registrant was given until 11/1/89 (9 months from 2/1/89) to supply the efficacy data for these products. The current submissions consist of reports of efficacy trials for the two products. These reports were submitted on 11/1/89.

201.0 DATA SUMMARY

The efficacy studies were run at the College of Veterinary Medicine of Mississippi State University under the direction of Dr. James G. Miller, a long-time d-Con consultant. Tests were said to have followed EPA's Protocols 1.203 and 1.204. Test phase durations were modified to include 3 days of bait exposure and 10 days of post-exposure observation. These modifications of the usual 15 days of exposure and 5 days of observation often are adopted for Brodifacoum baits so that the claim "Kills rats and mice in one feeding" maybe made. Mice were group-caged for the trials with 3282-66, but were caged individually for the trials with 3282-81. For the mouse trials with 3282-66, mice were housed in groups of ten animals (5 females, 5 males) in metal cages that were much larger than the upper limit specified in Protocol 1.204. I do not find the cage size used to be unacceptable, however, as I believe larger cages to be an improvement on the limits set in Protocol 1.204.

Subjects for the rat tests were CD strain albino Norway rats from Charles River Laboratories and Swiss-Webster strain house mice.

Table 1. Results of laboratory efficacy trials with d-Con Brodifacoum baits 3282-66 and 3282-81.

Product	Test	% Acceptance	% Mortality	Days to Death
3282-66	Rats #1	34.6%	100%	3-6
	Rats #2	42.3%	100%	3-6
	Mice #1	33.5%	95%	2-12
	Mice #2	25.7%	100%	3-8
3282-81	Rats #1	27.9%	95%	3-12
	Rats #2	18.1%	90%	4-12
	Mice #1	41.4%	100%	3-8
	Mice #2	42.3%	95%	6-12

Results of these trials are summarized in Table 1. As can be seen from these data, the baits were not particularly well accepted. Bait acceptance was below the criterion of 33% in several trials, including both replicates or rat tests with 3282-81. It appears that the bait preparation in that product is not very attractive to Norway rats. Three survivors (among 40 rats exposed to 3282-81) is a relatively high proportion for a Brodifacoum laboratory test.

None of these laboratory efficacy tests can be accepted at this time as d-Con did not submit raw data sheets or even data tables for individual animals or group-caged subgroups. This information should be requested, with rapid submission required as a condition of continued registration. As no new testing would be needed for such a submission, the material should be provided within 30 days.

202.0 CONCLUSIONS

The following comments apply to 3282-66:

1. Review of the efficacy data submitted for this product cannot be completed until data tables and copies of raw data sheets are submitted which show bait consumption by individual animals (rat tests) or individual test groups (mouse tests). Conditional registration will continue if this information is provided within 30 days.

The following comments apply to 3282-81:

1. Review of the efficacy data submitted for this product cannot be completed until data tables and copies of raw data sheets are submitted which show bait consumption by individual animals. Conditional registration will if this information is provided within 30 days of the date of this letter.

2. The summary data submitted suggest that this bait would not perform well enough against Norway rats to warrant continuation of rat claims on the label. Therefore, you must submit new efficacy data which show that the current formulation is adequately accepted (33%) by rats, delete rat claims from the product label, or amend the formulation to one that is well accepted by (and lethal to) Norway rats. The effectiveness of the new formulation is affective would have to be documented through laboratory efficacy studies.

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
May 14, 1990

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

[redacted]

November 17, 1989

Mr. William H. Miller (PM-16)
Insecticide - Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall, Building 2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Efficacy Data Generated For:
d-Con Ready Mixed Generation II
EPA Reg. No. 3282-81

Dear Mr. Miller:

In compliance with the conditional registration of the above d-Con rodenticide enclosed are three copies of the following efficacy report:

MRID# 41398201

1. Laboratory efficacy study for d-Con Ready Mixed Generation II- In Mice and Rats.(3282-81)

Thank you for your cooperation.

Sincerely,

John J. Domanski, Ph.D
Director of Toxicology

Lehn & Fink Products Group, *Sterling Drug Inc.*
225 Summit Avenue, Montvale, New Jersey 07645 / 201 573-5700

December 20, 1989

Mr. William H. Miller (PM-16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall, Building 2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: d-Con Ready Mixed Generation II
EPA Registration No. 3282-81
Your letter dated February 1, 1989

Dear Mr. Miller:

In compliance with the conditional registration of the above d-Con rodenticide, enclosed are five (5) copies of the product label for both the individual 3 oz. bait tray and the outer carton.

Thank you for your cooperation.

Sincerely,

John J. Domanski, Ph.D
Director of Toxicology

NOT REVIEWED
In Accordance [illegible]
Date 2/1/89

d-CON READY MIXED GENERATION II

KILLS RATS AND MICE 4 READY-TO-USE BAIT TRAYS

KILLS WARFARIN-RESISTANT NORWAY RATS AND WARFARIN-RESISTANT HOUSE MICE

IF PRODUCT OR PERFORMANCE DEFECTIVE • Good Housekeeping • PROMISES REPLACEMENT OR REFUND TO CONSUMER

d-CON®

READY MIXED GENERATION II

KILLS RATS AND MICE

READY-TO-USE BAIT TRAYS

KILLS WARFARIN-RESISTANT NORWAY RATS AND WARFARIN-RESISTANT HOUSE MICE.

Flavor attractive to rats and mice. Palatable formulation.

ADVANCED ANTICOAGULANT FORMULA CAN KILL IN ONE FEEDING*

Keep out of reach of children.

CAUTION: May be harmful or fatal if swallowed. Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:

Brodifacoum 3-[3-(4'bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one	0.005%
INERT INGREDIENTS	99.995%
TOTAL	100.000%

NET CONTENTS 4/3.0 OZ. (85g) NET WT. 12 OZ. (340g)

*RATS AND MICE WILL DIE WITHIN 4 OR 5 DAYS

d-CON READY MIXED GENERATION II

KILLS RATS AND MICE 4 READY-TO-USE BAIT TRAYS

d-CON READY MIXED GENERATION II ADVANCED ANTICOAGULANT FORMULA

KILLS RATS AND MICE

Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

NOT REVIEWED
In Accordance with PR Notice 83-2
Based on [illegible]
2/1/89

EPA Reg. No. 3282-81
EPA Est. No. 3282-OH-1

See Bottom of Box

SATISFACTION GUARANTEED OR YOUR MONEY BACK

B-318KP-89

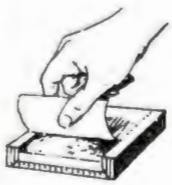
d-CON. READY MIXED GENERATION II

KILLS RATS AND MICE

ADVANCED ANTICOAGULANT FORMULA

d-CON Ready Mixed Generation II can kill in one feeding when used as directed. Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.



USE RESTRICTIONS: For control of Norway Rats, Roof Rats and House Mice in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. Do not use in sewers. This product must be placed in tamper-resistant bait boxes or in locations not accessible to children, pets, domestic animals or wildlife. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS: Place trays in or near points where you have seen rat or mice signs such as droppings, runways, burrows, or gnawing marks. Once areas requiring baiting have been identified proceed as follows:

APPLICATION DIRECTIONS:

1. Place one ready-to-use bait tray in each potential feeding location. Place trays in dark, out-of-the-way locations, where rodents are likely to find them. Do not place trays in the open or in any location exposed to children or nontarget mammals or birds.

For House Mice: Use only one tray per location.

For Norway and Roof Rats: Start with one tray per location. Add trays, up to a maximum of four per location, if you determine that there is high rat activity at the location.

2. If bait must be applied in areas accessible to children or nontarget animals, trays must be placed in secured, sturdy, tamper-resistant bait stations which deny these nontarget species access to the bait.

3. For best results, leave trays undisturbed for at least two days after placement. However, if contents have been scattered or mostly consumed sooner, replace trays. Clean up spilled bait. Check bait every two days, replacing trays as needed or until signs of rodent activity cease. Trays not fed from for five consecutive days may be relocated as needed. When there are no longer any signs of rodent activity, dispose of trays properly.

For complete control, continue baiting for at least 15 days. If you are in an area where there is a danger of reinfestation from adjoining property, permanent bait stations should be maintained. Stations should be checked periodically.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

STORAGE AND DISPOSAL:

Store in original container in areas inaccessible to small children and pets. Bait that cannot be used according to label instructions must be disposed of according to applicable federal, state, or local procedures.

KILLS WARFARIN-RESISTANT NORWAY RATS
AND WARFARIN-RESISTANT HOUSE MICE

d-CON.
READY MIXED
GENERATION II
ADVANCED
ANTICOAGULANT
FORMULA

KILLS RATS AND MICE

d-CON.
AMERICA'S
#1
RAT KILLER

Advanced Anticoagulant Formula
CAN KILL IN ONE FEEDING

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
2/1/85

SATISFACTION GUARANTEED OR YOUR MONEY BACK

Distributed by:
THE d-CON COMPANY INC.
A Subsidiary of Sterling Drug Inc.
225 Summit Avenue
Montvale, New Jersey 07645 U.S.A.

KP 92250

DT-0192-001
10-T0192-001

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION *(TS-767)*
WASHINGTON, DC 20460

NOTICE OF PESTICIDE: ☒ REGISTRATION ☐ REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION NO.	DATE OF ISSUANCE
3282-81	2/1/89

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT
d-Con Ready Mixed
Generation II

NAME AND ADDRESS OF REGISTRANT *(Include ZIP code)*

The d-Con Company, Inc.
Division of Sterling Drug, Inc.
225 Summit Avenue
Montvale, NJ 07645

16 228,830 3
38 237,409 3
16 18

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment:

   a. Add the phrase "EPA Registration No. 3282-81."

   b. Delete the caption "TAMPER-PROOF BAIT BOX" from the pictures of bait stations that are to be illustrated on the label for the box. Although the unit pictured appears to be reasonably sturdy and is illustrated as being locked, the unit does not appear to be capable of preventing a child from reaching through the rodent entrances and into the bait compartment. EPA considers use of this illustration to be a short-term compromise approach at best, to serve until standard bait station language is released for incorporation into labels for all baits registered to control commensal rodents. EPA does not want the bait station illustration on your labels to attain status as a valid depiction of a "TAMPER-PROOF BAIT BOX." As the current picture is better than no illustration, it should remain for now, but with the caption deleted.

☒ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

53949:I:Palmateer:LM-5:KENCO:1/31/89:4/25/89:rw:vo:rw

3. The following conditions are placed upon this registration.

a. Within 15 months of the date on this Registration Notice, you must submit the results of a storage stability test. The test must be of 1 year's duration as an "accelerated" test is not acceptable.

b. With 9 months of the date on this Registration Notice, submit the results of an efficacy test conducted both on rats and mice. The test results must demonstrate 90 percent or better mortality and 33 percent or better acceptance in both rats and mice.

4. The Confidential Statement of Formula dated December 5, 1988 is acceptable.

5. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosures

Front Panel
(Box)

d-CON
READY MIXED GENERATION II

4 READY-TO-USE BAIT TRAYS
ADVANCED ANTICOAGULANT FORMULA
*Can kill in one feeding

Kills Rats & Mice
KILLS WARFARIN-RESISTANT NORWAY RATS
AND WARFARIN-RESISTANT HOUSE MICE.

*RATS AND MICE WILL DIE WITHIN 4 OR 5 DAYS

GOOD HOUSEKEEPING SEAL:
Good Housekeeping promises a limited warranty to consumers. Replacement or refund if defective.

Flavor attractive to rats and mice
Palatable Formulation

ACTIVE INGREDIENT: Brodifacoum
3-[3-(4'bromo-[1,1'-biphenyl]-4-yl)-
1,2,3,4-tetrahydro-1-napthalenyl]-4-
hyroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS 99.995%

TOTAL 100.000%

NET WT. 12 OZ. (340g)
NET CONTENTS 4/3.0 OZ. (85g)

CAUTION: Keep out of reach of children
may be harmful or fatal if swallowed
Read additional precautionary statements
on side panel

BOTTOM OF BOX
d-CON Kills Rats & Mice
Ready Mixed Generation II

KILLS WARFARIN-RESISTANT NORWAY RATS
AND WARFARIN-RESISTANT HOUSE MICE

ACCEPTED
with COMMENTS
In EPA Letter Dated:

FEB 01 1989

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

32682-81

RIGHT SIDE PANEL
(BOX)

d-CON

READY MIXED GENERATION II
ADVANCED ANTICOAGULANT FORMULA

Kills

Rats & Mice

From d-CON
America's #1
Rat Killer

Advanced
Anticoagulant
Formula

Can Kill
in One Feeding

Satisfaction
Guaranteed or
Your Money Back

The d-CON Company Inc.
Subsidiary of Sterling Drug
225 Summit Avenue
Montvale, New Jersey 07645 U.S.A.

LEFT SIDE PANEL
(BOX)

d-CON

READY MIXED GENERATION II
ADVANCED ANTICOAGULANT FORMULA

Kills Rats & Mice

Kills
Warfarin-Resistant
Norway Rats and
Warfarin-Resistant
House Mice

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDRIECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

EPA Reg. No. 3282-
EPA Est. No. 3282-OH-1 or 2393-WI-1
See Bottom of Box

Satisfaction
Guaranteed or
Your Money Back

BACK PANEL
(BOX)

d-CON® READY MIXED GENERATION II ADVANCED ANTICOAGULANT FORMULA

Kills Rats & Mice

d-CON Pellets Generation II can kill in one feeding when used as directed. Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: For control of Norway Rats, Roof Rats and House Mice in and around homes, industrial, commercial, agricultural and public buildings. d-CON Pellets Generation II may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. Do not use in sewers. This product must be placed in tamper-resistant bait boxes or in locations not accessible to children, pets, domestic animals or wildlife. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS: Place trays in or near points where you have seen rat or mice signs such as droppings, runways, burrows, or gnawing marks. Once areas requiring baiting have been identified proceed as follows:

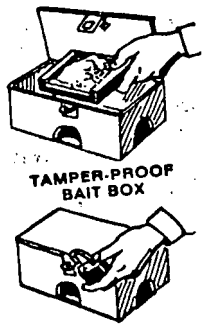
APPLICATION DIRECTIONS:

1. Place one ready-to-use bait tray in each potential feeding location. Place trays in dark, out-of-the way locations, where rodents are likely to find them. Do not place trays in the open or in any location exposed to children or nontarget mammals or birds.

BACK PANEL
(BOX) (CONTINUED)

For House Mice: Use only one tray per location.

For Norway and Roof Rats: Start with one tray per location. Add trays, up to a maximum of four per location, if you determine that there is high rat activity at the location.



2. If bait must be applied in areas accessible to children or nontarget animals, trays must be placed in secured, sturdy, tamper-resistant bait stations which deny these nontarget species access to the bait.

3. For best results, leave trays undisturbed for at least two days after placement. However, if contents have been scattered or mostly consumed sooner, replace trays. Clean up spilled bait. Check bait every two days, replacing trays as needed or until signs of rodent activity cease. Trays not fed from for five consecutive days may be relocated as needed. When there are no longer any signs of rodent activity, dispose of trays properly.

For complete control, continue baiting for at least 15 days. If you are in an area where there is danger or reinfestation from adjoining property, permanent bait stations should be maintained. Stations should be checked periodically.

NOTE: Underline denotes bold face type

BACK PANEL (Continued)
(BOX)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:
This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

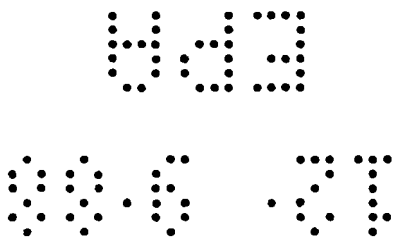
STORAGE AND DISPOSAL:
Store in original container in areas inaccessible to small children and pets. Bait that cannot be used according to label instructions must be disposed of according to applicable federal, state, or local procedures.

TOP PANEL
(BOX)

d-CON READY MIXED GENERATION II

Kills Rats and Mice

4 Ready-To-Use Bait Trays



FRONT PANEL
(BAIT TRAY)

d-Con$_R$

READY MIXED GENERATION II

Kills Rats & Mice

READY-TO-USE BAIT TRAY

ADVANCED ANTICOAGULANT FORMULA
*Call kill in one feeding

KILLS WARFARIN-RESISTANT NORWAY RATS

KILLS WARFARIN-RESISTANT HOUSE MICE

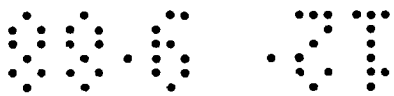
CAUTION: KEEP OUT OF REACH OF CHILDREN
May be harmful or fatal if swallowed.
Read additional precautionary statements on side panel.

ACTIVE INGREDIENT: Brodifacoum
3-[3-(4'-bromo-[1,1'biphenyl]-4-yl)-
1,2,3,4-tetrahydro-1-napthalenyl]-4-hyroxy-2H-1-
benzoyran-2-one.....0.005%
INERT INGREDIENTS 99.995%

TOTAL 100.000%

*First dead rodents will appear four or five days after treatment begins.

NET WT. 3.0 OZ. Bait Tray (85 g)



ACCEPTED
with COMMENTS
In EPA Letter Dated:

FEB 01 1989

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

32642-81

BACK PANEL
(BAIT TRAY)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
Place bait in areas not accessible to children, pet, domestic animals or wildlife or in tamper resistant bait boxes.

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call you local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrahaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.
FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.

See outer box for complete Directions for Use.

THE D-CON COMPANY, INC.
Subsidiary of Sterling Drug, Inc., 225 Summit Avenue, Montvale, NJ 07645 U.S.A.

IRB BRANCH REVIEW - TSS

Record Number(s)

237409

IN 1/4/89 OUT 1/18/89

EFFICACY

FILE OR REG. NO. 3282-IR

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 12/9/88

DATE OF SUBMISSION 12/6/88

DATE SUBMISSION ACCEPTED 1/4/89

TYPE PRODUCTS(S): I, D, H, F, N, R[x], S

DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 16

PRODUCT NAME(S) d-CON READY MIXED GENERATION II

COMPANY NAME The d-Con Company, Inc.

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 0.005% Brodifacoum dry bait in 3-oz. bait trays

Efficacy Review: d-CON READY MIXED GENERATION II, 3282-IR
The d-Con Company, Inc.
Montvale, NJ 07645

200.0 INTRODUCTION

200.1 Uses

A 0.005% Brodifacoum crushed pellet bait proposed for registration to control Norway rats, roof rats, and house mice "in and around homes, industrial, commercial, agricultural and public buildings." As with many other d-Con rat and mouse baits, this product would be sub-packaged in 3-oz. bait trays.

200.2 Background Information

See efficacy reviews of 7/9/88 and 12/29/88, along with other information in product jacket. This is an amended registration application. Not all of the comments in the efficacy review of 7/9/88 were relayed to the applicant in time to be incorporated into the efficacy review of 12/29/88. Comments from that review have not been sent to registrant. Some of those comments are no longer applicable due to registrant's having made changes requested in the efficacy review of 7/9/88 (and EPA's letter of 9/16/88). The comments in the "CONCLUSIONS" section of this review are the efficacy comments which still apply to this product.

Tte product is said to be made by crushing the pellets of "d-CON^{R} LIM-N8™ Rat Killer, EPA Registration no. 3282-74 to a crumbled product. The efficacy review of 7/9/88 discussed results of efficacy tests with an earlier formulation of this product which contained Rhodamine B dye, an "inert of concern". Many of the tests were reported only in a table that summarized results of tests with many batches of 3282-74. These data showed that bait acceptance by laboratory Norway rats ("CD" albino strain) was below the 33% criterion for anticoagulant baits. Acceptance by rats of the batch of 3282-74 from which the test batch of 3282-IR was said to have been made was slightly above criterion. These results suggested that crumbling the formulation made it less palatable than it had been in pelleted form. Results of the efficacy tests with Swiss-Webster strain house mice were acceptable, although acceptance was somewhat lower for the crumbled bait than for pellets (3282-74) from the same batch.

As the product has been reformulated by removing Rhodamine B, the old efficacy data are not completely relevant to the new formulation. In its amended applications, d-Con has requested conditional registration until efficacy studies can be run with the new formulation. In the current submission, d-Con states that it wants to run its efficacy studies of a "large factory batch" produced "under actual manufacturing conditions". d-Con adds that

> "The material produced would be held for shipment until said tests were completed to the satisfaction of the Agency."

d-Con's offer to wait begs a question. Why does d-Con want conditional registration if it truly does not intend to sell the production batch until EPA says that the efficacy data are acceptable?

The current submission includes revised labels for the bait trays and the outer box, a new Confidential Statement of Formula (CSF), assorted forms, and a report of an analysis of particle sizes of the crumbled bait.

201.0 DATA SUMMARY

No new efficacy data were submitted. As the efficacy data on the "old" proposed formulation were acceptable only for house mice, there is no past history of acceptable performance of this product for Norway rats. Therefore, the only conditional registration that I could recommend would be for a house-mouse-only label.

The label comments in previous reviews have been addressed for the most part. I have a problem with direct labeling of the bait station to be illustrated on the box as a "TAMPER-PROOF BAIT BOX". Although the unit appears to be reasonably sturdy and is illustrated as being locked, it appears that a child could reach the bait compartment by reaching through the rodent entrances. It would be very inconvenient for EPA if that picture of a station were to attain status as a depiction of a "TAMPER-PROOF BAIT BOX" is. The picture is better than nothing. For now, it could remain if the caption were deleted.

202.0 CONCLUSIONS

1. Delete the caption "TAMPER-PROOF BAIT BOX" from the pictures of bait stations that are to be illustrated on the label for the box. Although the unit pictured appears to be reasonably sturdy and is illustrated as being locked, the unit does not appear to be capable of preventing a child from reaching through the rodent entrances and into the bait compartment. EPA considers use of this illustration to be a short-term compromise approach at best, to serve until standard bait station language is released for incorporation into labels for all baits registered to control commensal rodents. EPA does not want the bait station illustration on your labels to attain status as a valid depiction of a "TAMPER-PROOF BAIT BOX". As the current picture is better than no illustration, it should remain, for now, but with the caption deleted.

2. Submit efficacy data to support the claims made for this product. Bait acceptance was marginally below criterion for rats tested with the "old" formulation. Thus, the only data potentially available for tentative support of the rat claim suggest possible efficacy problems. Such data do not provide an adequate basis for a conditional registration

   Crumbling the old formulation also appeared to lower bait acceptance by mice, although acceptable efficacy data for house mice were generated with the "old" formulation (containing Rhodamine B) for this product. Your request for conditional registration could be honored at this time only if you were to delete claims for control of Norway and roof rats.

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
January 18, 1989

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME: ~~Bromacil~~ Brodifacoum

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
3282-IR	161	None	5. RECORD NUMBER: 237409
			6. REFERENCE NUMBER: 3
			7. DATE RECEIVED (EPA): 12-09-88
			8. STATUTORY DUE DATE: 2-09-89
			9. PRODUCT MANAGER (PM): MILLER
			10. PM TEAM NUMBER: 16

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS: 01-04-89

12. PRIORITY NUMBER:

13. PROJECTED RETURN DATE:

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD

D. ☒ TSS/RD

E. ☐ Other

F. INSTRUCTIONS

RODENTICIDE!

Please enclose 2 Copies of review and return to Steve

16. RELATED ACTIONS

17. 3(c)(1)(D)
- ● Use Any or All Available Information ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO
- ☐ TB ☐ EEB ☐ EF ☐ PL
- ☐ RCB ☐ EFB ☐ CH ☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
HED	ECOLOGICAL EFFECTS								
HED	RESIDUE CHEMISTRY								
HED	ENVIRONMENTAL DATE								
RD/TSS	CHEMISTRY								
RD/TSS	X EFFICACY 1/18/89 OBS/MMS	1							
RD/TSS	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20.	21.	22.	23.	24.
☐ Label Submitted with Application Attached	☐ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

EPA Form 8570-13 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE.

CERTIFICATION WITH RESPECT TO CITATION OF DATA

EPA File Symbol/Reg. No. 3282-IR Date of application 4-4-88

Name of Product d-CON^{R} Ready Mixed Generation II

Applicant's Name and Address The d-CON Company

Subsidiary of Sterling Drug, Inc.

225 Summit Avenue

Montvale, New JErsey 07645

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

[ ] All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (Cite-all method or cite-all option under Selective Method). (Also sign the General Offer to Pay Statement below.)

[XX] Those companies who have submitted the studies which I have cited (Selective method)

Date 12-2-88 Signature Robert L. Lee

Title Director, EPA Registrations/ Rodenticides

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Date _____ Signature _____

Title _____

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

December 6, 1988

Mr. William H. Miller (PM-16)
Insecticide - Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall, Building 2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: d-CON^R Ready Mixed Generation II
EPA File Symbol 3282-IR
Your Letter Dated September 16, 1988

Dear Mr. Miller:

With reference to your response of September 16, 1988 on the subject topic, I discussed the various points made in your letter via telephone with Mr. Steve Palmateer on November 14th and came to a general agreement with him on our responses to those points. The following, taken in the order appearing in your September 16th letter, will confirm my conversation with Mr. Palmateer:

1. a. In view of the fact that our brodifacoum concentrate has been reformulated, we have absolutely no problem in rerunning the efficacy tests. We do ask, however, that we be given a conditional registration pending the outcome of these tests. We would prefer to produce a large factory batch under actual manufacturing conditions for the efficacy studies. The material produced would be held for shipment until said tests were completed to the satisfaction of the Agency. In our telephone conversation, Mr. Palmateer indicated that this approach would be agreeable to the Agency.

2. b. For marketing reasons, the subject product will actually be "crumbled" ready-to-use d-CON^R LIM-N8 Rat Killer (Pellets), EPA Registration No. 3282-74, that have been crushed to a specific sieve size in a roller mill. This will be the exact

manufacturing process used when this product is registered. The manufacturing process submitted for Formula DD-5022 (MRID No. 406325-01) will be the same as that used for the subject product, i.e., d-CON^{R} Ready Mixed Generation II. The sieve size for the subject product was submitted with our original application dated April 4, 1988; please refer to page 6, Volume II - Product Chemistry Studies. Another copy is attached for your convenience.

1.c. New efficacy data is being generated.

2. Certification With Respect to Citation of Data

A new form that is filled out correctly is attached.

3. Confidential Statement of Formula (CSF)

A new CSF which corrects the deficiencies noted in your letter is attached.

4. Label Revisions - The Rhodamine B statement has been deleted.

Five (5) copies of the revised label are attached for your files.

Thank you for your prompt attention to this matter. Needless to say, we are rather anxious to proceed with the marketing of this product. Your expeditious approval of the subject pending registration would be greatly appreciated.

Sincerely,

Robert L. Bruns
Director, EPA Registrations/Rodenticides

RLB:RF
Attachments

READY MIXED

containing

BRODIFACOUM

Manufacturing process information may be entitled to confidential treatment

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME: Brodifacoum

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
3282-IR	101		5. RECORD NUMBER 228830
			6. REFERENCE NUMBER 3
			7. DATE RECEIVED (EPA) 6-27-88
			8. STATUTORY DUE DATE 9-21-88
			9. PRODUCT MANAGER (PM) MILLER
			10. PM TEAM NUMBER 16

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS 08-30-88

12. PRIORITY NUMBER

13. PROJECTED RETURN DATE

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

C. ☐ BFSD
D. ☒ TSS/RD
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

RODENTICIDE! INERT SUBSTITUTION FOR

Please enclose 2 Copies of review and return to Steve

16. RELATED ACTIONS: up FILE IN TSS REVIEW 8/31/88 please work

17. 3(c)(1)(D)
- ☒ Use Any or All Available Information
- ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO
- ☐ TB
- ☐ EEB
- ☒ EF
- ☐ PL
- ☐ RCB
- ☐ EFB
- ☒ CH
- ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
HED		ECOLOGICAL EFFECTS								
HED		RESIDUE CHEMISTRY								
HED		ENVIRONMENTAL DATE								
RD/TSS	X	CHEMISTRY	1							
RD/TSS	X	EFFICACY OSS/WMT 12/29/87	1							
RD/TSS		PRECAUTIONARY LABELING								
BFSD		ECONOMIC ANALYSIS								

20.	21.	22.	23.	24.
☒ Label Submitted with Application Attached	☒ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

IRB BRANCH REVIEW - TSS

Record Number(s)

228830

IN 12/17/88 OUT 12/29/88

EFFICACY

FILE OR REG. NO. 3282-IR

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 6/27/88

DATE OF SUBMISSION 6/27/88

DATE SUBMISSION ACCEPTED 12/17/88

TYPE PRODUCTS(S): I, D, H, F, N, Rx, S

DATA ACCESSION NO(S). no new efficacy data

PRODUCT MGR. NO. 16

PRODUCT NAME(S) d-CON READY-MIXED GENERATION II

COMPANY NAME The d-Con Company, Inc.

SUBMISSION PURPOSE Registration, formulation change

CHEMICAL & FORMULATION 0.005% Brodifacoum dry bait

Efficacy Review: d-CON READY MIXED GENERATION II, 3282-IR
The d-Con Company, Inc.
Montvale, NJ 07645

200.0 INTRODUCTION

200.1 Uses

A 0.005% Brodifacoum crushed pellet bait proposed for registration to control Norway rats, roof rats, and house mice "in and around homes, industrial, commercial, agricultural and public buildings. As with many other d-Con rat and mouse baits, this product would be sub-packaged in 3-oz. bait trays.

200.2 Background Information

See efficacy review of 7/9/88 and other information in product jacket. This is an amended registration application. As not all of the comments in the efficacy review of 7/9/88 were relayed to the applicant, some of the thoughts will be repeated in this review.

The applicant claims that the product formulation is identical to that of "d-CON® LIM-N8™ Rat Killer," EPA Registration no. 3282-74, in every way except physical form." The new product is said to be made by "crushing the LIM-N8 pellets to a crumbled product with a specific sieve analysis and bulk density". The efficacy review of 7/9/88 discussed results of efficacy tests with an earlier formulation (containing Rhodamine B dye, an "inert of concern") of this product and of summarized results of tests with many batches of 3282-74. These data showed that bait acceptance by laboratory Norway rats ("CD" albino strain) was below the 33% criterion for anticoagulant baits. Acceptance by rats of the batch of 3282-74 form which the test batch of 3282-IR was said to have been made was slightly above criterion. These results suggested that crumbling the formulation rendered it less palatable than it had been in pelleted form. Results of the efficacy tests with laboratory house mice (Swiss-Webster) were acceptable, although acceptance was somewhat lower for the crumbled bait than for pellets (3282-74) from the same batch.

As the product has been reformulated by removing Rhodamine B, the old efficacy data are not completely relevant to the new formulation. In its amended application, d-Con requests conditional registration "until we can conduct these (efficacy) studies."

201.0 DATA SUMMARY

No new efficacy data were submitted. As the efficacy data on the "old" proposed formulation were acceptable only for house mice, there is no past history of acceptable performance of this product for Norway rats. Therefore, the only conditional registration that I could recommend would be for a house-mouse-only label.

The label comments presented under "CONCLUSIONS" are similar to comments that have been made for 3282-66, another d-Con bait that is to be subpackaged in 3-oz. bait trays.

202.0 CONCLUSIONS

1. In last sentence of item #1 under "APPLICATION DIRECTIONS", insert "trays" between "place" and "in the open".

2. Add the illustrations of bait stations to this label that are to be used with 3282-66. Note that the Agency believes that 3-oz. bait trays provide much more bait per placement than is advisable for house mouse control. However, such directions may appear on your label for the time being, at least.

3. Submit efficacy data to support the claims made for this product. As acceptable efficacy data for house mice were generated with the "old" formulation (containing Rhodamine B) for this product, the request for conditional registration could be honored if you were to delete claims for control Norway and roof rats.

   Acceptance was marginally below criterion for rats in tests with the "old" formulation. Thus, the only data potentially available for tentative support of the rat claim suggest possible efficacy problems. In fact, crumbling the old formulation appeared to lower bait acceptance for both test species.

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
December 29, 1988

FRONT PANEL
(BOX)

6/27/88
SUBMISSION

d-CON
READY MIXED GENERATION II

4 READY-TO-USE BAIT TRAYS OR 16 READY-TO-USE BAIT TRAYS OR 24 ETC.
ADVANCED ANTICOAGULANT FORMULA
*Can Kill in one feeding

6-27-88

Kills Rats & Mice
KILLS WARFARIN-RESISTANT NORWAY RATS
AND WARFARIN-RESISTANT HOUSE MICE.

EPA

*RATS AND MICE WILL DIE WITHIN 4 OR 5 DAYS

GOOD HOUSEKEEPING SEAL:
Good Housekeeping promises a limited warranty to consumers. Replacement or refund if defective.

Flavor attractive to rats and mice
Palatable Formulation

ACTIVE INGREDIENT: Brodifacoum
3-[3-(4'bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-napthalenyl]-4-hyroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS 99.995%

TOTAL 100.000%

NET WT. 12 OZ. (340 g)
NET CONTENTS 4/3.0 OZ. (85 g)

OR

NET WT. 3 LBS.
NET CONTENTS 16/3 OZ.

OR

NET WT. 4 LBS. 8 OZ.
NET CONTENTS 24/3 OZ.

CAUTION: Keep out of reach of children
May be harmful or fatal if swallowed
Read additional precautionary statements on side panel

Bottom of Box
d-CON Kills Rats & Mice
Ready Mixed Generation II

KILLS WARFARIN-RESISTANT NORWAY RATS
AND WARFARIN-RESISTANT HOUSE MICE

TOP PANEL
(BOX)

d-CON READY MIXED GENERATION II

Kills Rats and Mice

4 Ready-To-Use Bait Trays

OR

16 READY-TO-USE BAIT TRAYS

OR

24 READY-TO-USE BAIT TRAYS

6·27·88

EPA

RIGHT SIDE PANEL
(BOX)

d-CON

READY MIXED GENERATION II
ADVANCED ANTICOAGULANT FORMULA

Kills

Rats & Mice

From d-CON
America's #1
Rat Killer

Advanced
Anticoagulant
Formula

Can Kill
in One Feeding

Satisfaction
Guaranteed or
Your Money Back

The d-CON Company Inc.
Subsidiary of Sterling Drug
225 Summit Avenue
Montvale, New Jersey 07645 U.S.A.

6-27-88

EPA

LEFT SIDE PANEL
(BOX)

d-CON

READY MIXED GENERATION II
ADVANCED ANTICOAGULANT FORMULA

Kills Rats & Mice

Kills
Warfarin-Resistant
Norway Rats and
Warfarin-Resistant
House Mice

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions,,or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

EPA Reg. No. 3282-
EPA Est. No. 3282-OH-1 or 2393-WI-1
See Bottom of Box

Satisfaction
Guaranteed or
Your Money Back

6-27-88

EPA

BACK PANEL
(BOX)

d-CON® Kills
READY MIXED GENERATION II Rats &
ADVANCED ANTICOAGULANT FORMULA Mice

d-CON Ready Mixed Generation II can kill in one feeding when used as directed. Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

DIRECTIONS FOR USE:
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: For control of Norway Rats, Roof Rats and House Mice in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. Do not use in sewers. This product must be placed in tamper-resistant bait boxes or in locations not accessible to children, pets, domestic animals or wildlife. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS: Place trays in or near points where you have seen rat or mice signs such as droppings, runways, burrows, or gnawing marks. Once areas requiring baiting have been identified proceed as follows:

APPLICATION DIRECTIONS:
1. Place one ready-to-use bait tray in each potential feeding location. Place trays in dark, out-of-the-way locations, where rodents are likely to find them. Do not place in the open or in any location exposed to children or nontarget mammals or birds.

For House Mice: Use only one tray per location.

For Norway and Roof Rats: Start with one tray per location. Add trays, up to a maximum of four per location, if you determine that there is high rat activity at the location.

2. If bait must be applied in areas accessible to children or nontarget animals, trays must be placed in secured, sturdy, tamper-resistant bait stations which deny these nontarget species access to the bait.
3. For best results, leave trays undisturbed for at least two days after placement. However, if contents have been scattered or mostly consumed sooner, replace trays. Clean up spilled bait. Check bait every two days, replacing trays as needed or until signs of rodent activity cease. Trays not fed from for five consecutive days may be relocated as needed. When there are no longer any signs of rodent activity, dispose of trays properly.

For complete control, continue baiting for at least 15 days. If you are in an area where there is danger of reinfestation from adjoining property, permanent bait stations should be maintained. Stations should be checked periodically.

NOTE: Underline denotes bold face type.

BACK PANEL (Continued)
(BOX)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.
FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:
This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

STORAGE AND DISPOSAL:
Store in original container in areas inaccessible to small children and pets. Bait that cannot be used according to label instructions must be disposed of according to applicable federal, state, or local procedures.

FRONT PANEL
(BAIT TRAY)

d-CON®
READY MIXED GENERATION II

Kills Rats & Mice

READY-TO-USE BAIT TRAY

ADVANCED ANTICOAGULANT FORMULA
*Can kill in one feeding

KILLS WARFARIN-RESISTANT NORWAY RATS

KILLS WARFARIN-RESISTANT HOUSE MICE

CAUTION: KEEP OUT OF REACH OF CHILDREN
May be harmful or fatal if swallowed.
Read additional precautionary statements on side panel.

ACTIVE INGREDIENT: Brodifacoum
3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-
1,2,3,4-tetrahydro-1-napthalenyl]-4-hyroxy-2H-1-
benzopyran-2-one 0.005%
INERT INGREDIENTS 99.995%

TOTAL 100.000%

*First dead rodents will appear four or five days after treatment begins.

NET WT. 3.0 Oz. Bait Trays (85 g)

8-27-86

EPA

BACK PANEL
(BAIT TRAY)

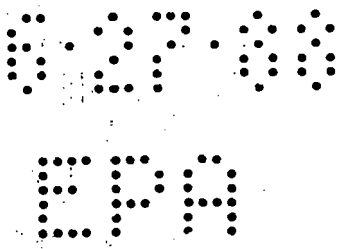
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper resistant bait boxes.

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.
FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.

See outer box for complete Directions for Use.

THE d-CON COMPANY, INC.
Subsidiary of Sterling Drug, Inc., 225 Summit Avenue, Montvale, NJ 07645 U.S.A.



Form Approved. OMB No. 2070-0060. Approval expires 9-30-90.

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAM (TS-767)
WASHINGTON, D.C. 20460

APPLICATION FOR PESTICIDE: ☐ REGISTRATION ☒ AMENDMENT A

Please read instructions on reverse before completing.

SECTION I

1. COMPANY/PRODUCT NO.	2. DATE	3. PRODUCT MANAGER	4. PROPOSED CLASSIFICATION
3282-IR	6/27/88	W. Miller (PM-16)	☒ GENERAL ☐ RESTRICTED

5. NAME AND ADDRESS OF APPLICANT *(Include ZIP Code)*

The d-Con Company Inc.
Subsidiary of Sterling Drug, Inc.
225 Summit Avenue
Montvale, New Jersey 07645

☐ CHECK IF THIS IS A NEW ADDRESS

6. PRODUCT NAME

d-Con® Ready Mixed Generation II

SECTION II

1. SUBJECT OF AMENDMENT

☐ RESUBMISSION IN RESPONSE TO AGENCY LETTER DATED _____

☐ FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED _____

☒ OTHER *(explain below)*

Label amendment (due to formula change), i.e., delete list 1 inert, Rhodamine B, from formula and label.

SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN:

CHILD-RESISTANT PACKAGING ☐ YES ☐ NO

UNIT PACKAGING ☐ YES ☐ NO
If YES; unit pkg. wt. _____ No. per container _____

WATER-SOLUBLE PACKAGING ☐ YES ☐ NO
If YES, pkg. wt. _____ No. per container _____

2. TYPE OF CONTAINER

☐ METAL ☐ PLASTIC ☐ GLASS ☐ PAPER ☐ OTHER *(Specify)*

3. LOCATION OF NET CONTENTS ☐ LABEL ☐ CONTAINER

4. SIZE(S) OF RETAIL CONTAINER

5. LOCATION OF LABEL DIRECTIONS ☐ ON LABEL ☐ ON MATERIAL ACCOMPANYING PRODUCT

6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT ☐ LITHOGRAPH ☐ OTHER *(Specify)* ☐ PAPER GLUED ☐ STENCILED

SECTION IV

1. CONTACT POINT *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application).*

NAME: John J. Domanski, Ph.D.

TITLE: Director of Toxicology

TELEPHONE NO. *(Include Area Code)*: 201-573-7673

2. SIGNATURE: John J. Domanski

3. TITLE: Director of Toxicology

4. TYPED NAME: John J. Domanski, Ph.D.

5. DATE SIGNED

6. DATE APPLICATION RECEIVED *(Stamped)*

EPA Form 8570-1 (Rev. 5-81) PREVIOUS EDITION IS OBSOLETE.

INSTRUCTIONS

GENERAL

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). *(If not exempted by 40 CFR [illegible].)*
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mock-up of the proposed label. If prepared as a mock-up it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mock-up labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

ALL DATA FOR WHICH CLAIMS OF CONFIDENTIALITY ARE ASSERTED MUST BE SUBMITTED, BOUND SEPARATELY AND CLEARLY MARKED AS SUCH.

SPECIFIC

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in BLOCK A, for which you are submitting this application. For applications submitted in connection with NEW REGISTRATION actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

BLOCK A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both REGISTRATION and AMENDED REGISTRATION actions.

1. Company/Product Number - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. Date - Fill in the appropriate date.
3. Product Manager - If known, fill in the name and number of the Product Manager.
4. Proposed Classification - Specify the proposed classification for this product.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

   An applicant NOT residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

AMENDMENT INFORMATION

Section II - This Section must be completed for all applications submitted in connection with AMENDED REGISTRATION.

1. Subject of Amendment - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements", etc.

PACKAGING AND CONTAINER INFORMATION

Section III - This Section must be completed for all applications submitted in connection with NEW REGISTRATION.

1. Type of Packaging - Check the appropriate block if you product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the statement of net contents.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Direction - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product labeling is attached to retail container.

CONTACT POINT

Section IV - This Section must be completed for all REGISTRATION and AMENDED REGISTRATION applications.

1-5. Self-explanatory.

6. EPA Use Only.

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

June 27, 1988

Mr. William H. Miller (PM-16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U. S. Environmental Protection Agency
Crystal Mall, Building #2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Miller:

Re: d-CON Ready Mixed Generation II
EPA File Symbol 3282-IR
Application for Amended Petition

The d-CON Company, Inc., Subsidiary of Sterling Drug, Inc., wishes to amend its application dated April 4, 1988. This amendment is necessary because [redacted] by removing Rhodamine B and substituting another dye. Since the Rhodamine B is no longer present, the "Toxic Inert Ingredient" statement is no longer appropriate. Therefore, we are submitting amended labels deleting the "Rhodamine B" statement from the revised label submitted with the April 4, 1988 application. There are no other changes to this label.

Attached is a completed Application for Pesticide Amendment (EPA Form 8570-1, Rev. 5-81) and five (5) copies of the revised label.

I understand that the Agency may require additional efficacy data. d-Con agrees to conduct any appropriate studies, but requests that we be granted a conditional registration until we can conduct these studies. I also understand that it will not be necessary for d-CON to submit a revised Confidential Statement of Formula (CSF) because [redacted] will be identical to the old product. If, however, the Agency requires a new CSF, please call me (201-573-7673) and I will submit the information as soon as possible.

As far as the alleged deficiencies in our original application that were listed in your letter dated May 9, 1988, I understand that this matter has been cleared up. R. Bruns of my office spoke to Ms. Maureen Sheryl and it was determined that there were no deficiencies and that the application was being processed as submitted.

.....cont'd.....

Product ingredient source information may be entitled to confidential treatment

If any part of this application is deficient, we request the Agency consider granting us a conditional registration. Anything that you can do to expedite the processing of this petition would be greatly appreciated.

Sincerely

John J. Domanski, Ph.D.
Director of Toxicology

JJD:ck
Enc.

16 SEP 1988

223,646

161
13

BRUNS

Mr. Robert L. Burns
The d-Con Company, Inc.
Subsidiary of Sterling Drug, Inc.
225 Summit Avenue
Montvale, NJ 07645

Dear Mr. Burns:

Subject: d-Con Ready Mixed Generation II
EPA File Symbol 3282-IR
Your Application Dated March 4, 1988

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reasons given below.

1. The Agency has reviewed your product efficacy data (MRID No. 406325-02) and does not find it applicable to the product you intend to sell for the following reasons:

   a. The brodifacoum concentrate has been reformulated; therefore, your efficacy tests were conducted on the old product.

   b. It is unclear that the product sold over-the-counter will actually be the same as the ready-to-use product (EPA Registration No. 3282-74) that has been crushed in a roller mill. Will this be the exact manufacturing process used when this product is registered? Will the manufacturing process (MRID No. 406325-01) you submitted for "Formula DD-5022" be the same as that used for the subject product "d-Con Ready Mixed Generation II? Also, with your next submission please submit the sieve size of the subject product.

   The Agency can make your storage stability test conditional upon registration but considering all the uncertainties cannot make the efficacy requirement conditional for this pending registration. As you are aware, the Agency has allowed the efficacy requirement to be submitted later for many of your registered products but these products did not have so many unanswered questions.

53285:I:Palmateer:CBI-13:KENCO:9/13/88:12/8/88:CT:VO:JH:aw

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

c. We note the tested formulation had only marginal efficacy for rats and assume any new data that incorporates the appropriate formulation will be more efficacious.

2. Certification With Respect to Citation of Data - You did not indicate whether you were using the Selective Method or the Cite-All Method. Please resubmit the form.

3. Confidential Statement of Formula (CSF) - Your CSF dated April 4, 1988 indicates your product will not meet the label claim. Also, columns 14.a. and 14.b. must be the percent pure active ingredient not percent of concentrate. Please resubmit a new CSF.

4. Label revisions - Delete the Rhodamine B statement.

Sincerely yours,

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

FRONT PANEL
(BOX)

d-CON
READY MIXED GENERATION II

4 READY-TO-USE BAIT TRAYS OR 16 READY-TO-USE BAIT TRAYS OR 24 ETC.
ADVANCED ANTICOAGULANT FORMULA
*Can Kill in one feeding

Kills Rats & Mice
KILLS WARFARIN-RESISTANT NORWAY RATS
AND WARFARIN-RESISTANT HOUSE MICE.

*RATS AND MICE WILL DIE WITHIN 4 OR 5 DAYS

GOOD HOUSEKEEPING SEAL:
Good Housekeeping promises a limited warranty to consumers. Replacement or refund if defective.

Flavor attractive to rats and mice
Palatable Formulation

ACTIVE INGREDIENT: Brodifacoum
3-[3-(4'bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-napthalenyl]-4-hyroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS 99.995%

TOTAL 100.000%

The product contains the toxic inert ingredient Rhodamine B.

NET WT. 12 OZ. (340 g)
NET CONTENTS 4/3.0 OZ. (85 g)

OR

NET WT. 3 LBS.
NET CONTENTS 16/3 OZ.

OR

NET WT. 4 LBS. 8 OZ.
NET CONTENTS 24/3 OZ.

CAUTION: Keep out of reach of children
May be harmful or fatal if swallowed
Read additional precautionary statements on side panel

Bottom of Box
d-CON Kills Rats & Mice
Ready Mixed Generation II

KILLS WARFARIN-RESISTANT NORWAY RATS
AND WARFARIN-RESISTANT HOUSE MICE

TOP PANEL
(BOX)

d-CON READY MIXED GENERATION II

Kills Rats and Mice

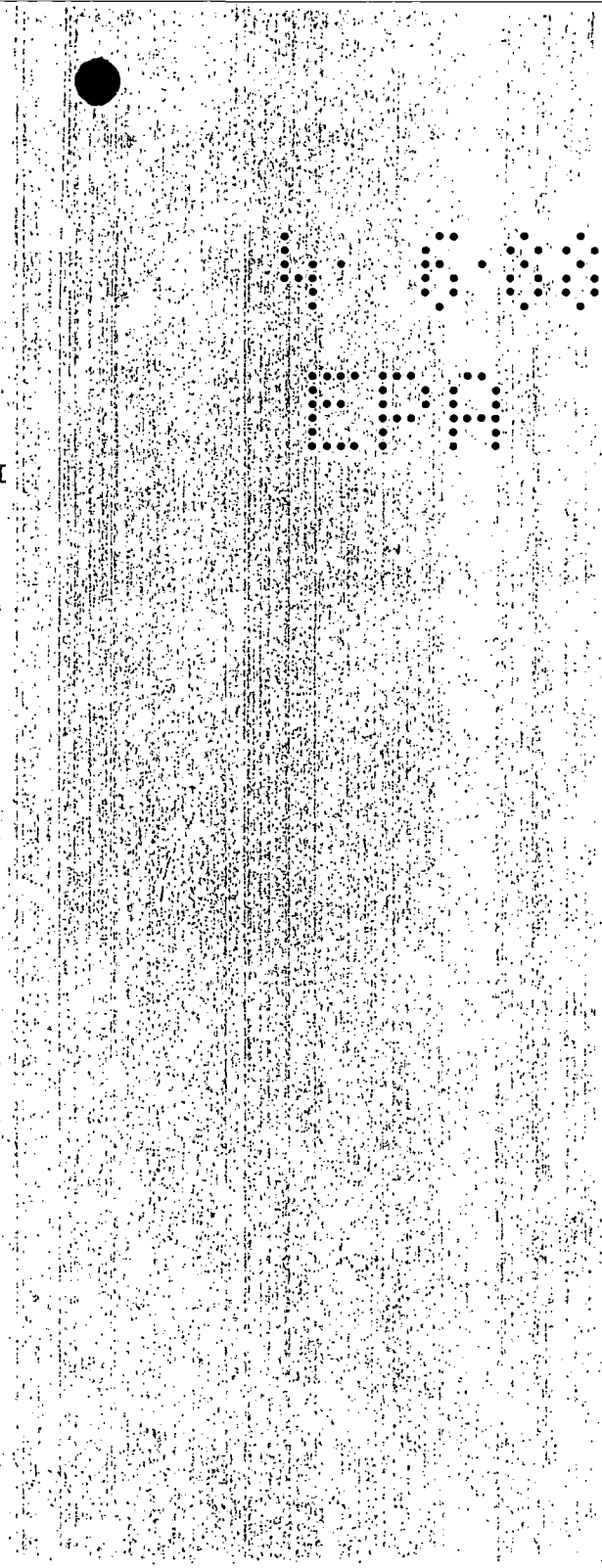
4 Ready-To-Use Bait Trays

OR

16 READY-TO-USE BAIT TRAYS

OR

24 READY-TO-USE BAIT TRAYS



RIGHT SIDE PANEL
(BOX)

d-CON

READY MIXED GENERATION II
ADVANCED ANTICOAGULANT FORMULA

Kills

Rats & Mice

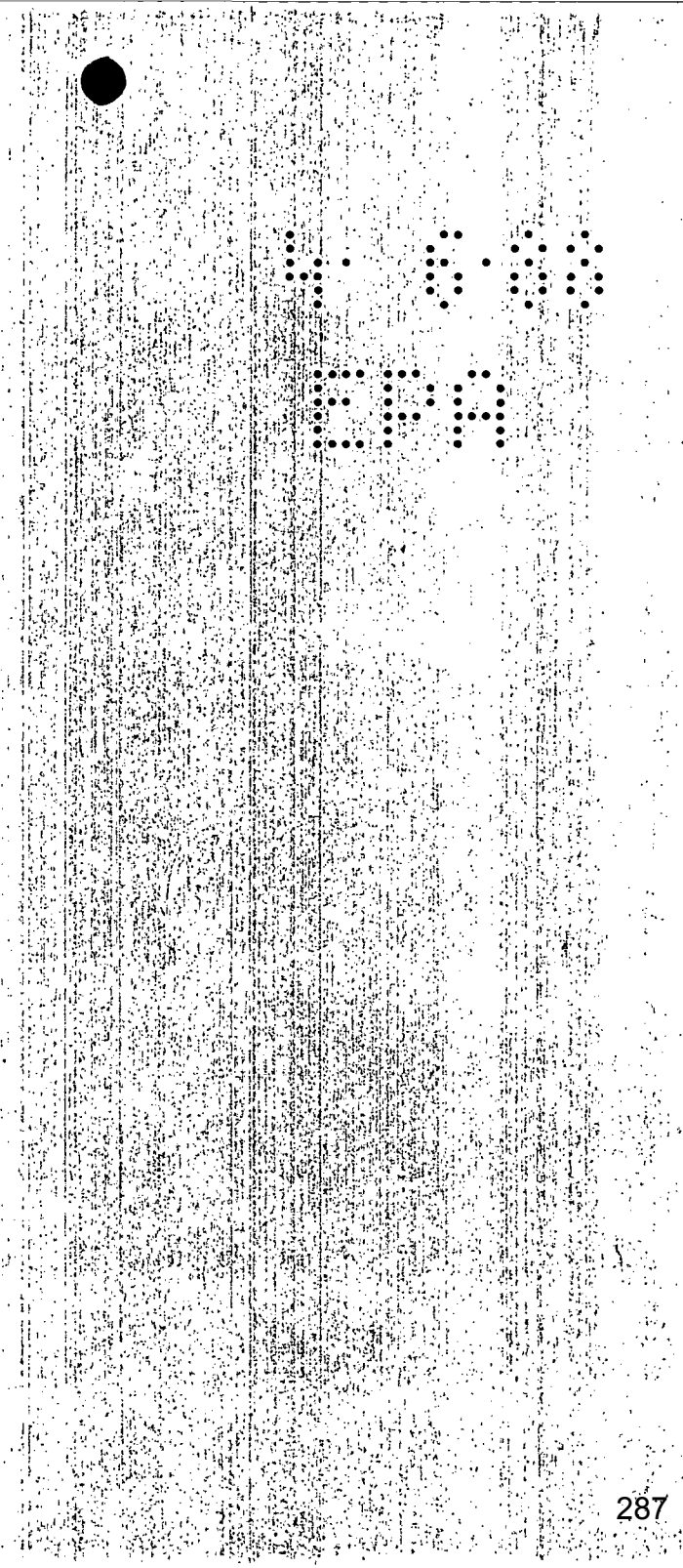
From d-CON
America's #1
Rat Killer

Advanced
Anticoagulant
Formula

Can Kill
in One Feeding

Satisfaction
Guaranteed or
Your Money Back

The d-CON Company Inc.
Subsidiary of Sterling Drug
225 Summit Avenue
Montvale, New Jersey 07645 U.S.A.



LEFT SIDE PANEL
(BOX)

d-CON

READY MIXED GENERATION II
ADVANCED ANTICOAGULANT FORMULA

Kills Rats & Mice

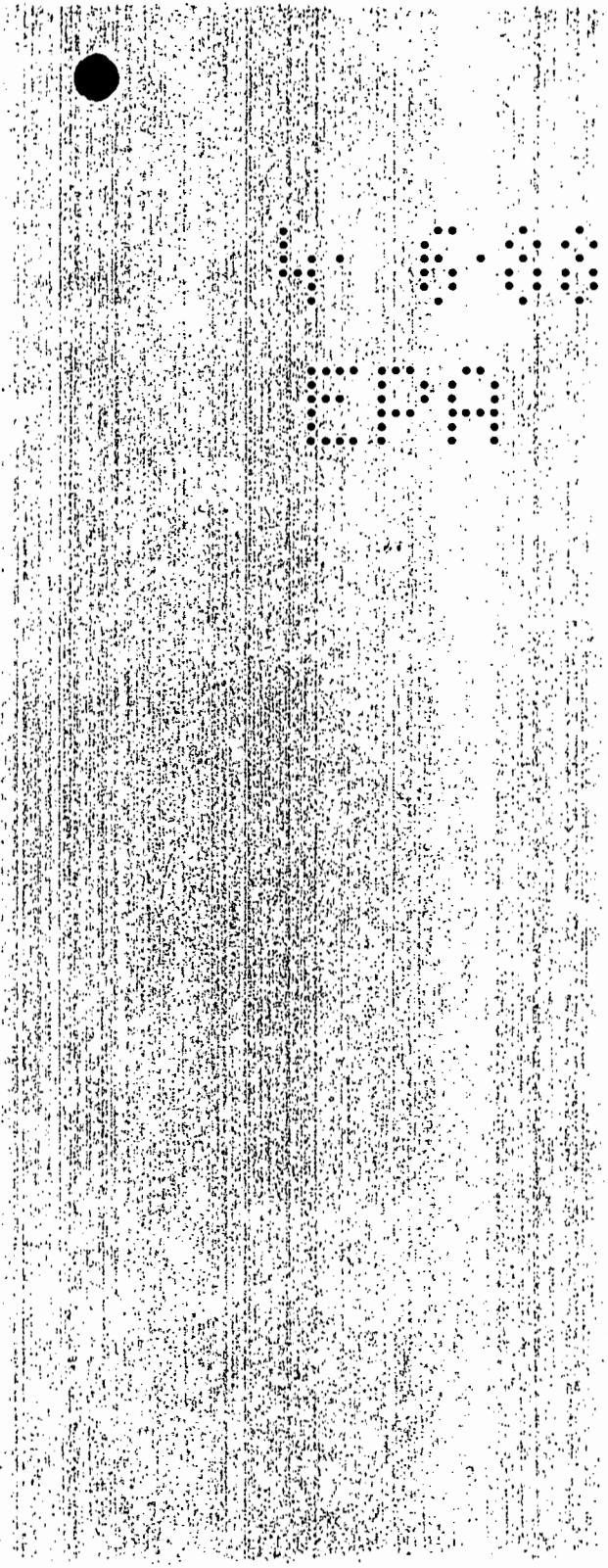
Kills
Warfarin-Resistant
Norway Rats and
Warfarin-Resistant
House Mice

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions,.or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

EPA Reg. No. 3282-
EPA Est. No. 3282-OH-1 or 2393-WI-1
See Bottom of Box

Satisfaction
Guaranteed or
Your Money Back



BACK PANEL
(BOX)

d-CON® Kills
READY MIXED GENERATION II Rats &
ADVANCED ANTICOAGULANT FORMULA Mice

d-CON Ready Mixed Generation II can kill in one feeding when used as directed. Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

DIRECTIONS FOR USE:
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: For control of Norway Rats, Roof Rats and House Mice in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. Do not use in sewers. This product must be placed in tamper-resistant bait boxes or in locations not accessible to children, pets, domestic animals or wildlife. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS: Place trays in or near points where you have seen rat or mice signs such as droppings, runways, burrows, or gnawing marks. Once areas requiring baiting have been identified proceed as follows:

APPLICATION DIRECTIONS:
1. Place one ready-to-use bait tray in each potential feeding location. Place trays in dark, out-of-the-way locations, where rodents are likely to find them. Do not place in the open or in any location exposed to children or nontarget mammals or birds.

For House Mice: Use only one tray per location.

For Norway and Roof Rats: Start with one tray per location. Add trays, up to a maximum of four per location, if you determine that there is high rat activity at the location.

2. If bait must be applied in areas accessible to children or nontarget animals, trays must be placed in secured, sturdy, tamper-resistant bait stations which deny these nontarget species access to the bait.
3. For best results, leave trays undisturbed for at least two days after placement. However, if contents have been scattered or mostly consumed sooner, replace trays. Clean up spilled bait. Check bait every two days, replacing trays as needed or until signs of rodent activity cease. Trays not fed from for five consecutive days may be relocated as needed. When there are no longer any signs of rodent activity, dispose of trays properly.

For complete control, continue baiting for at least 15 days. If you are in an area where there is danger of reinfestation from adjoining property, permanent bait stations should be maintained. Stations should be checked periodically.

NOTE: Underline denotes bold face type.

BACK PANEL (Continued)
(BOX)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.
FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:
This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

STORAGE AND DISPOSAL:
Store in original container in areas inaccessible to small children and pets. Bait that cannot be used according to label instructions must be disposed of according to applicable federal, state, or local procedures.

FRONT PANEL
(BAIT TRAY)

d-CON®
READY MIXED GENERATION II

Kills Rats & Mice

READY-TO-USE BAIT TRAY

ADVANCED ANTICOAGULANT FORMULA
*Can kill in one feeding

KILLS WARFARIN-RESISTANT NORWAY RATS

KILLS WARFARIN-RESISTANT HOUSE MICE

CAUTION: KEEP OUT OF REACH OF CHILDREN
May be harmful or fatal if swallowed.
Read additional precautionary statements on side panel.

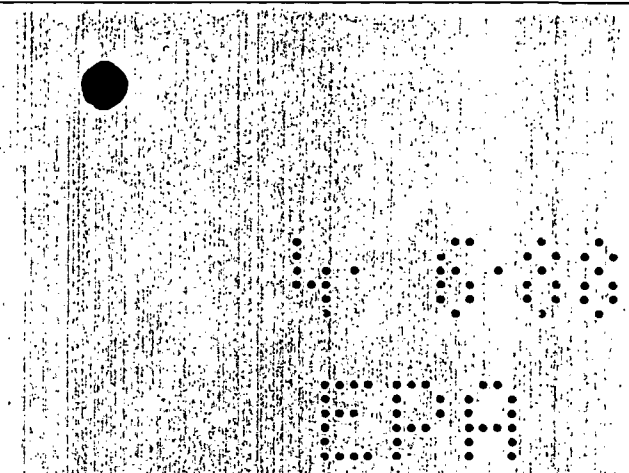
ACTIVE INGREDIENT: Brodifacoum
3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-napthalenyl]-4-hyroxy-2H-1-benzopyran-2-one 0.005%
INERT INGREDIENTS 99.995%

TOTAL 100.000%

The product contains the toxic inert ingredient Rhodamine B.

*First dead rodents will appear four or five days after treatment begins.

NET WT. 3.0 Oz. Bait Trays (85 g)



BACK PANEL
(BAIT TRAY)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper resistant bait boxes.

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.
FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.

See outer box for complete Directions for Use.

THE d-CON COMPANY, INC.
Subsidiary of Sterling Drug, Inc., 225 Summit Avenue,
Montvale, NJ 07645 U.S.A.

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME: Brodifacoum

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER
3282-IR	161	406325

TO BE COMPLETED BY PM

5. RECORD NUMBER: 223646
6. REFERENCE NUMBER: 1
7. DATE RECEIVED (EPA): 06-03-88
8. STATUTORY DUE DATE: 09-13-88
9. PRODUCT MANAGER (PM): MILLER
10. PM TEAM NUMBER: 16

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS: 06-03-88
12. PRIORITY NUMBER:
13. PROJECTED RETURN DATE:

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD
D. ☒ TSS/RD
E. ☐ Other

F. INSTRUCTIONS

RODENTICIDE!

Please enclose 2 Copies of review and return to Steve

16. RELATED ACTIONS

17. 3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB ☐ EEB ☐ EF ☐ PL
☐ RCB ☐ EFB ☐ CH ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
HED		ECOLOGICAL EFFECTS								
HED		RESIDUE CHEMISTRY								
HED		ENVIRONMENTAL DATE								
RD/TSS	X	CHEMISTRY OBJ JPK 8-22-88	1							
RD/TSS	X	EFFICACY 7/10 RF 7 HR OBJECTIONS	1							
RD/TSS		PRECAUTIONARY LABELING								
BFSD		ECONOMIC ANALYSIS								

20.	21.	22.	23.	24.
☒ Label Submitted with Application Attached	☒ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

EPA Form 9570-12 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE

Reg. # 3282-IR Product name D-Con Ready Mixed Gen. II
Rec. #

PRODUCT CHEMISTRY CHECKLIST

Please provide the requested information for the following checked items:

1. [X] Submit the product specific product chemistry and the data matrix for your product. Your product is not sufficiently similar to the product you referenced. ONLY Manufacturing process submitted

2. On the Confidential Statement of Formula (CSF) please provide the following:

[ ] a) Provide pH of product or pH at a specified water dilution.
[ ] b) density of product
[ ] c) flash point of product
*[ ] d) flash point of product with the propellent.
[ ] e) flame extension of product including flashbacks if noted
[X] f) ~~Provide the upper and lower Certified Limits based on the pure active ingredients rather than the technical or concentrate.~~ Note that the lower limit of the active must be the same as the label claim in pure active form. (146 of CSF should be Label Claim)
[ ] g) Provide upper and lower Certified Limits of the individually added inerts.
[ ] h)
[ ] i)

3. [X] Based on the current CSF dated 4/4/88 your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so the information agrees.

4. [ ] Please provide the chemical identity of all components, MSDS and CAS #s of:(two copies reqd)
1)
2)
3)
The supplier may contact us directly referencing your file symbol/EPA Reg. # in their response.
For dyes, color index and CAS #s for all components are required. For perfumes and flavoring all chemical components by CAS #s and % in the mixture must be identified. Certify that flavors are of non-food type.

5. [X] Please update the label Storage and Disposal Statement per PR 83-3 or ~~PR-84-1.~~

6. [ ] Add a footnote to the label ingredient statement indicating:
Contains petroleum distillates, xylene, xylene range aromatic solvent

7. [ ] Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement. See 40 CFR 162.10

8. [ ] Since your data matrix does not give a dielectrical breakdown voltage, you must add the following to the use directions:
Do not use this product in or on electrical equipment due to the possibility of shock hazard.

9. [ ] Solvent used is not considered an active ingredient so either report it under inert ingredients on the label or provide the registration no. for the source product and justify its insecticidal properties.

(see back page)

Reg. # _____

CHEMISTRY CHECKLIST CONT'D

9. Data Matrix Requirements

[ ] a) Statement of Composition - a complete description of the manufacturing/formulation process. Describe equipment used, mixing time, temperature etc.

[ ] b) Discussion of Formation of [Unintentional] Ingredients - a brief description of impurities formed during the manufacturing/formulation process, in packaging, or during storage. If you do not expect any impurities during these stages, please so state.

[ ] c) Certification of Limits - upper and lower limits of each active and individually added inert component. The lower limit for the actives, must be the same as the label claim in pure active ingredient form.

[ ] d) Analytical Method - provide the methods used to analyze for the active ingredients.

[ ] e) Color - in common terms.

[ ] f) Physical State - e.g. solid, liquid, pressurized liquid, etc.

[ ] g) Odor - in common terms.

[ ] h) Density - e.g. lbs/gallon for liquids or lbs/cu. ft. for solids.

[ ] i) pH - provide pH of product or pH of a specified water dilution.

[ ] j) Oxidizing or Reducing - note these characteristics if any.

* [ ] k) Flammability - flash point/flame extension.

[ ] l) Explodability - note these characteristics if any.

[ ] m) Storage Stability - the formulated product must be analyzed for its active ingredient at time zero and during a year of storage. The storage should be in warehouse conditions of temperature and humidity and stored in similar containers you will be using in the trade. Note: For the Storage Stability study you cannot reference the concentrate you are using to formulate your product.

[ ] n) Viscosity - can be expressed in centipoise or centistokes.

[ ] o) Miscibility - note these characteristics if product is an emulsifiable liquid and mixed with oil.

[ ] p) Corrosion Characteristics - this information can be noted during the storage stability study.

[ ] q) Dielectric Breakdown Voltage - for products used near electrical equipment.

obj JPK 8-22-88

Notes: 1) Environmental Hazards statement incomplete.

IRB BRANCH REVIEW - TSS

Record Number(s)

223646

IN 6/3/88 OUT 7/10/88

EFFICACY

FILE OR REG. NO. 3282-IR

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 4/6/88

DATE OF SUBMISSION 4/4/88

DATE SUBMISSION ACCEPTED 6/3/88

TYPE PRODUCTS(S): I, D, H, F, N, Rx S

DATA ACCESSION NO(S). 406325-00 406325-01 406325-02

PRODUCT MGR. NO. 16

PRODUCT NAME(S) d-CON READY MIXED GENERATION II

COMPANY NAME The d-Con Company, Inc.

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 0.005% Brodifacoum dry bait

Product ingredient source information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

Efficacy Review: d-CON READY MIXED GENERATION II, 3282-IR
The d-Con Company, Inc.
Montvale, NJ 07645

200.0 INTRODUCTION

200.1 Uses

A 0.005% Brodifacoum crushed pellet bait proposed for registration to control Norway rats, roof rats, and house mice "in and around homes, industrial, commercial, agricultural and public buildings. As with many other d-Con rat and mouse baits, this product would be sub-packaged in 3-oz. bait trays.

200.2 Background Information

This is a new application, or at least the first time that a submission for this product has passed the "screen". The applicant claims that the product formulation is identical to that of "d-CON^{R} LIM-N8™ Rat Killer, EPA Registration no. 3282-74, in every was except physical form." The new product is said to be made by "crushing the LIM-N8 pellets to a crumbled product with a specific sieve analysis and bulk density".

201.0 DATA SUMMARY

The manufacturing process statement submitted for this product indicates that [redacted]

The proposed label states that the product contains Rhodamine B. [redacted]

Although the product is said to correspond in ingredient composition to a registered product (3282-74) for which efficacy data have been accepted, the applicant is still required to run efficacy studies on the new product as bait form can have a profound effect on the acceptance and, therefore, the efficacy of rodenticide baits. In fact, the efficacy data submitted by d-Con demonstrates that altering the form of the bait affects its efficacy. In this case, the effect was negative -- over a small, but critical, range.

d-Con submitted reports of two separate efficacy test each for laboratory Norway rats ("CD" albino strain, Charles River Laboratories) and for laboratory mice (Swiss-Webster strain). Test protocols used were reported to be the "acute" methods (1.209 for rats, 1.210 for mice). These methods are often used for "second-generation" anticoagulants such as Brodifacoum justify the "single-feeding" claim on the label. The main difference between these methods and the methods traditionally used for antcoagulant baits (1.203 for rats, 1.204 for mice) is that the acute methods use only a 3-day bait exposure period rather than the 15-day period used in the anticoagulant tests. OPP's policy has been to permit use of the 3-day exposure period but to require that the 33% bait acceptance criterion for anticoagulants be met.

The efficacy tests were run at the College of Veterinary Medicine, Mississippi State University, under the direction of James G. Miller, a long-time consultant for d-Con. The mouse test was modified somewhat. Four groups of five animal each were run instead of the 20-animal group test described in the protocol or the separate testing of 10 males and 10 females that is the most common alternative methodology followed in mouse tests. In Dr. Miller's tests, all animals in a five-animal group were of the same sex. The smaller groups were used "to reduce problems of access to the bait." I actually prefer the five-animal group size. This size has enough animals to enable sufficiently accurate measurement of bait consumption (which is difficult with singly-caged house mice) and does reduce competition for bait, thus making the test more of a choice test and less of a demonstration of animals taking what is available.

Dr. Miller also culled and replaced "aggressive animals" in the mouse tests. I agree with this procedure as it removes a possible confounding source of mortality (and bleeding); and it is likely that bait preferences and temperment are reasonably independent traits.

Three analyses of the test bait showed 0.0055%, 0.0056%, and 0.0057% Brodifacoum. These show good agreement and are within what should be acceptable limits of the amount (0.005%) claimed on the product label. The lowest of these amounts projects to the Brodifacoum concentrate in the product amounting a larger proportion of the bait than is claimed, even at the upper certified limit, in the CSF. As these certified limits are incorrectly specified anyway (the lower limit is below the nominal concentration), the best remedy would be to change the certified limits to accommodate reality. However, the problem of bait acceptance by rats would still remain.

Results in the efficacy tests reported for 3282-IR were as follows:

Species	Test	% Acceptance	% Mortality	Days to Death*
Norway rat	First	31.4%	90%	3 - 10
	Second	25.0%	90%	4 - 8
House mouse	First	45.3%	100%	4 - 13
	Second	48.8%	100%	4 - 10

* Victims only

Performance in the mouse tests exceeded EPA's anticoagulant bait criteria of 33% Acceptance and 90% Mortality. Results in the mouse test fell short of the Acceptance criterion and just met the Mortality figure. Data on individual rats showed that three of the four rats not killed in the two 20-animal tests consumed cumulative doses of Brodifacoum that were less than 2 mg/kg body weight. The fourth survivor took a cumulative dose of 6.45 mg/kg. One rat that died ingested a lower cumulative dose than did any of the survivors.

In his report, Dr. Miller also presents summary data of tests with LIM-N8, the alleged parent product to 3282-IR. Acceptance scores for 17 rat tests with LIM-N8 were listed. These scores ranged from 32.0% to 62.7%, suggesting either variability in bait palatablity between batches or variability in acceptance behavior of the laboratory rats used (which would be more likely only if different strains were used). However, only one of these scores rounded to a value less than the 33% Acceptance criterion. The batch of LIM-N8 ("TA 074") that was crumbled to make 3282-IR for the tests under consideration in this review was accepted by rats at 33.3% and 35.4% when tested in its original pelleted form (which assays found to be 0.0048-0.0049% Brodifacoum). Mortality was 95% in both LIM-N8 rat tests.

In two mouse tests, batch "TA 074" LIM-N8 was accepted at 53.3% and 55.1%, producing Mortality scores of 90% and 100%, respectively.

Crumbling the bait appears to make it less acceptable to both species. Acceptance was greater than 40% for 11 of 17 batches for which data were reported. Use of a relatively poorly accepted batch of LIM-N8 as a starting point for making 3282-IR probably resulted in the crumbled bait's failing the efficacy tests. If d-Con's (or their Brodifacoum supplier's) quality control were sufficient to keep LIM-N8's acceptance by rats well above 40%, the acceptance of 3282-IR would probably remain adequate (as opposed to the marginally useful range reported in the studies under discussion). I have difficulty comprehending why d-Con would want to go to extra effort (crumbling and sifting pellets) to make an inferior bait. (Note that lack of essentiality cannot be used as grounds for rejecting a pesticide application, although lack of efficacy can.)

I suspect that both LIM-N8 (3282-74) and 3282-IR products will be reformulated shortly to get rid of Rhodamine B dye.

Use directions on the proposed label are acceptable.

202.0 SUMMARY

Proposed use directions for this product are acceptable.

Efficacy data show acceptance by rats to be below the 33% criterion. (Note that the criterion holds for anticoagulants even if they are run in tests with only 3-days of bait exposure). To resolve this problem you may

1) re-test the current formulation in hopes that the results reported were unusually poor for the formulation,

2) reformulate to a more palatable formulation (and re-test),

3) delete rat claims from the label and register the current formulation as a mouse only-product (in which case trays should contain 2-oz. or less of bait), or

4) withdraw the application.

It appears that crumbling and sifting LIM-N8 pellets might also slightly suppress acceptance by mice, suggesting that going to the extra effort might not be justified.

William W. Jacobs
Biologist
IRB/TSS
July 9, 1988

ATTACHMENT A
FORMULATOR'S EXEMPTION STATEMENT

EPA File Symbol/Reg. No. 3282- **Product Name** d-CON(R) Ready Mixed Generation II

Applicant's Name and Address The d-CON Company, Inc.

Subsidiary of Sterling Drug, Inc.

225 Summit Avenue
Montvale, N. J. 07645

As an authorized representative of the applicant for registation of the product identified above, I hereby certify that:

(1) Our product is an end use product, and it contains the active ingredient(s): Brodifacoum

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling the appropriate text which paragraph applies—(A) or (B):

(A) An accurate Confidential Statement of Formula for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated _____ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active Ingredient	Source: Product Name and Reg. No.

Signature: Robert L. Bruns

Typed name: Robert L. Bruns

Director, Product Development

Dated: 4-4-88

CERTIFICATION WITH RESPECT TO CITATION OF DATA

EPA File Symbol/Reg. No. 3282- Date of application 4-4-88

Name of Product d-CON(R) Ready Mixed Generation II

Applicant's Name and Address The d-CON Company, Inc.

Subsidiary of Sterling Drug, Inc.

225 Summit Avenue

Montvale, N. J. 07645

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

[ ] All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (Cite-all method or cite-all option under Selective Method). (Also sign the General Offer to Pay Statement below.)

[ ] Those companies who have submitted the studies which I have cited (Selective method)

Date 4-4-88 Signature Robert L. Bruns

Title Robert L. Bruns
Director, Product Development

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Date _____ Signature _____

Title _____

COMPANY: The d-CON Company, Inc.
Subsidiary of Sterling Drug, Inc.
225 Summit Avenue
Montvale, New Jersey 07645

STUDY TITLE: Volume I - Administrative Materials for the Registration of d-CON^{R} Ready Mixed Generation II (EPA Registration No. 3282 -)

CONTENTS:

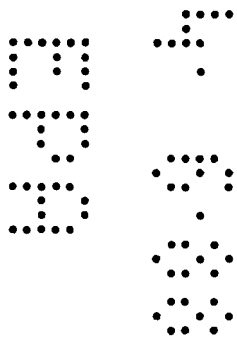
A. Application for Pesticide (EPA Form 8570-1; Rev. 5-81)

B. Confidential Statement of Formula (EPA Form 8570-4; Rev. 2-85)

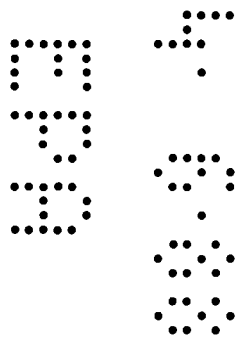
C. Formulator's Exemption Statement (40 CFR 152.85, 4/85)

D. Certification with Respect to Citation of Data (April 1985)

E. Five (5) Copies Each of the Prototype Labels.



COMPANY:	The d-CON COMPANY, INC. Subsidiary of Sterling Drug, Inc. 225 Summit Avenue Montvale, New Jersey 07645
STUDY TITLE:	Volume IV - Brodifacoum Support Data
DATA REQUIREMENT:	Guidelines 158.20, 158.135, 158.160
AUTHOR:	Not Known - Data not produced by submitter
STUDY COMPLETION DATE:	Not Known - Data not produced by submitter
PERFORMING LABORATORY:	Performed for/by ICI Americas Inc.



STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA S10(d) (1) (A), (B), or (C).

Company: The d-CON Company, Inc.
Subsidiary of Sterling Drug Inc.

Company Agent: Robert L. Bruns

Director, Product Development

Date: 4/4/88

ICI Americas Inc.

Agricultural
Products

February 4, 1988

Mr. William H. Miller
Product Management Team (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall 2, Room 223
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Miller:

RE: d-CON Ready Mixed Generation II
Letter of Authorization

The active ingredient in the subject product is the rodenticide brodifacoum. An application for registration for the subject product has been filed by d-CON. All ICI data to support registration of the active ingredient brodifacoum are contained or referenced in the following ICI Americas Inc. files: Registration Nos. 10182-28, 10182-29, 10182-48, 10182-25, 10182-38, 10182-39, 10182-40, 10182-41, 10182-61, 10182-60, 10182-75, and 10182-76.

This letter authorizes you to utilize any of the data contained or referenced in the above-mentioned ICI Americas' files in support of d-CON's registration.

PR Notice 83-4 provides that an original data submitter who has provided EPA with information on an active ingredient that would be subject to "exclusive use," FIFRA section 3(c)(1)(D)(i), will be notified by EPA of each application for registration of a product containing the active ingredient at least 30 days before the registration is approved. We waive our right to receive such notice for the subject product.

This authorization does not imply any waiver or abdication of our rights in these data, or any right to use these data by any party for any other use than specified herein.

Sincerely,

Diane L. Ierley

Diane L. Ierley
Pesticide Regulatory Specialist

DLI/sfp

020488SFP104

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

D-CON COMPANY INC.
225 SUMMIT AVENUE
NONTVALE, NJ 07645

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 04/06/88. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation.

If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

3282-IR

April 4, 1988

Mr. William H. Miller (PM-16)
Insecticide - Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall, Building 2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: d-CON^{R} Ready Mixed Generation II
EPA Registration No. 3282 -

Dear Mr. Miller:

The d-CON Company, Inc., Subsidiary of Sterling Drug Inc., wishes to make application for the registration of the subject new product, i.e., d-CON^{R} Ready Mixed Generation II. As indicated to Mr. Dan Peacock in our various telephone conversations during the week of March 21, the subject product is identical to our currently registered rodenticide, d-CON^{R} LIM-N8^{TM} Rat Killer, EPA Registration No. 3282-74, in every way except physical form. As a matter of fact, d-CON^{R} Ready Mixed Generation II is made by crushing the LIM-N8 pellets to a crumbled product with a specific sieve analysis and bulk density.

Per my discussions with Mr. Peacock, I am only including those documents for this registration which cannot be referenced from our LIM-N8 (EPA Registration No. 3282-74) file or the ICI Americas Inc. file for brodifcoum (letter of authorization attached). Necessary documents that are specific to this registration such as administrative materials/forms, manufacturing procedure, efficacy testing, etc., are included as follows:

ADMINISTRATIVE MATERIAL

Volume I - Administrative Materials

A. Application for Pesticide
(EPA Form 8570-1; Rev. 5-81)

B. Confidential Statement of Formula
(EPA Form 8570-4; Rev. 2-85)

ADMINISTRATIVE MATERIAL

C. Formulator's Exemption Statement
(40 CFR 152.85, 4/85)

D. Certification with Respect to Citation of Data
(April, 1985)

E. Five (5) copies each of the prototype lables.

40632501

Volume II - Product Chemistry Studies
(Guideline 158.20)

A. 61-2 Manufacturing Procedure

40632502

Volume III - Product Efficacy Evaluation
(Guideline 158.160)

A. Evaluation of d-CON[R]
Ready Mixed Generation II for effectiveness

ADMINISTRATIVE MATERIAL

Volume IV - Brodifacoum Support Data

A. ICI Americas Inc. - February 4, 1988 letter of authorization to reference brodifacoum information in EPA files with the following registration numbers: 10182-28, 10182-29, 10182-48, 10182-25, 10182-38, 10182-39, 10182-40, 10182-41, 10182-61, 10182-60, 10182-75 and 10182-76.

Thank you for your prompt attention to the subject application for registration. Anything you can do to expedite the approval of this application would be greatly appreciated. Should you have any questions whatsoever, please do not hesitate to call me at (201) 573-5846.

Sincerely,

Robert L. Bruns, Director
Product Development

RLB:RF
Enclo.

Form Approved. OMB No. 2000-0483. Approval expires 9-30-87

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAM (TS-767)
WASHINGTON, D.C. 20460

APPLICATION FOR PESTICIDE: [X] REGISTRATION [ ] AMENDMENT A

Please read instructions on reverse before completing.

SECTION I

1. COMPANY/PRODUCT NO.	2. DATE	3. PRODUCT MANAGER	4. PROPOSED CLASSIFICATION
3282- IR	4-4-88	W. Miller (PM-16)	[X] GENERAL [ ] RESTRICTED

5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code)

The d-CON Company, Inc.
Subsidiary of Sterling Drug, Inc.
225 Summit Avenue
Montvale, N. J. 07645

[ ] CHECK IF THIS IS A NEW ADDRESS

6. PRODUCT NAME
d-CON(R) Ready Mixed Generation II

SECTION II

1. SUBJECT OF AMENDMENT

[ ] RESUBMISSION IN RESPONSE TO AGENCY LETTER DATED _____

[ ] FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED _____

[ ] OTHER (explain below)

SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN:

CHILD-RESISTANT PACKAGING [ ] YES [X] NO

UNIT PACKAGING [X] YES [ ] NO
If YES; unit pkg. wt. 3 oz. No. per container 4, 16, 24

WATER-SOLUBLE PACKAGING [ ] YES [X] NO
If YES, pkg. wt. _____ No. per container _____

2. TYPE OF CONTAINER
[ ] METAL
[ ] PLASTIC
[ ] GLASS
[ ] PAPER
[X] OTHER (Specify)
cardboard

3. LOCATION OF NET CONTENTS
[X] LABEL [ ] CONTAINER

4. SIZE(S) OF RETAIL CONTAINER
12 oz., 3 lbs., 4 lbs. 8 oz.

5. LOCATION OF LABEL DIRECTIONS
[X] ON LABEL
[ ] ON MATERIAL ACCOMPANYING PRODUCT

6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT
[ ] LITHOGRAPH [X] OTHER (Specify) Printed
[ ] PAPER GLUED
[ ] STENCILED

SECTION IV

1. CONTACT POINT (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

NAME
Robert L. Bruns

TITLE
Director, Product Development

TELEPHONE NO. (Include Area Code)
(201)573-5846

2. SIGNATURE
Robert L. Bruns

3. TITLE
Director, Product Development

4. TYPED NAME
Robert L. Bruns

5. DATE SIGNED
4-4-88

6. DATE APPLICATION RECEIVED (Stamped)

EPA Form 8570-1 (Rev. 5-81) PREVIOUS EDITION IS OBSOLETE.

INSTRUCTIONS

GENERAL

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). *(If not exempted by 40 CFR 162.9-1(b).*
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mock-up of the proposed label. If prepared as a mock-up it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mock-up labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

ALL DATA FOR WHICH CLAIMS OF CONFIDENTIALITY ARE ASSERTED MUST BE SUBMITTED, BOUND SEPARATELY AND CLEARLY MARKED AS SUCH.

SPECIFIC

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in BLOCK A, for which you are submitting this application. For applications submitted in connection with NEW REGISTRATION actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

BLOCK A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both REGISTRATION and AMENDED REGISTRATION actions.

1. Company/Product Number - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. Date - Fill in the appropriate date.
3. Product Manager - If known, fill in the name and number of the Product Manager.
4. Proposed Classification - Specify the proposed classification for this product.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

   An applicant NOT residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

AMENDMENT INFORMATION

Section II - This Section must be completed for all applications submitted in connection with AMENDED REGISTRATION.

1. Subject of Amendment - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements", etc.

PACKAGING AND CONTAINER INFORMATION

Section III - This Section must be completed for all applications submitted in connection with NEW REGISTRATION.

1. Type of Packaging - Check the appropriate block if you product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the statement of net contents.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Direction - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product labeling is attached to retail container.

CONTACT POINT

Section IV - This Section must be completed for all REGISTRATION and AMENDED REGISTRATION applications.

1-5. Self-explanatory.

6. EPA Use Only.

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Mr. Robert L. Burns
The d-con Company, Inc.
225 Summit Avenue
Montvale, NJ 07645

Dear Mr. Burns:

Subject: Report of Analysis for Compliance with PR Notice 86-5
d-con Ready Mixed Generation II
EPA File Symbol 3282-IR
Your Application Dated April 4, 1988

Thank you for your transmittal of April 6, 1988. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

The rejected documents below are identified with numbers which correlate to those taken from your submitted bibliography.

(01)

Studies must be continuously paginated from the title page through the end of the study and all appendices--except for the Confidential Attachment or Supplemental Statement of Confidentiality Claims, if present--even when the study is large enough to span more than one physical volume.

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. See pages 8 and 13 of PR Notice 86-5.

11036:I:Palmateer:CBI-8:KENCO:4/15/88:5/26/88:Am:WB:EK:Am:ek:rw

CONCURRENCES

	ORIGIONATOR							
SYMBOL								
SURNAME	Tice							
DATE	MAY 9 1988							

OFFICIAL FILE COPY

We note that you claim your product contains the toxic inert "Rhodmanine B." It is our understanding that this product will no longer contain this dye. Please clarify.

Sincerely yours,

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

The d-Con Company Inc. / 225 Summit Avenue / Montvale, N.J 07645

April 4, 1988

Mr. William H. Miller (PM-16)
Insecticide - Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall, Building 2, Room 211
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: d-CON^{R} Ready Mixed Generation II
EPA Registration No. 3282 -

Dear Mr. Miller:

The d-CON Company, Inc., Subsidiary of Sterling Drug Inc., wishes to make application for the registration of the subject new product, i.e., d-CON^{R} Ready Mixed Generation II. As indicated to Mr. Dan Peacock in our various telephone conversations during the week of March 21, the subject product is identical to our currently registered rodenticide, d-CON^{R} LIM-N8^{TM} Rat Killer, EPA Registration No. 3282-74, in every way except physical form. As a matter of fact, d-CON^{R} Ready Mixed Generation II is made by crushing the LIM-N8 pellets to a crumbled product with a specific sieve analysis and bulk density.

Per my discussions with Mr. Peacock, I am only including those documents for this registration which cannot be referenced from our LIM-N8 (EPA Registration No. 3282-74) file or the ICI Americas Inc. file for brodifcoum (letter of authorization attached). Necessary documents that are specific to this registration such as administrative materials/forms, manufacturing procedure, efficacy testing, etc., are included as follows:

Volume I - Administrative Materials

A. Application for Pesticide
(EPA Form 8570-1; Rev. 5-81)

B. Confidential Statement of Formula
(EPA Form 8570-4; Rev. 2-85)

C. Formulator's Exemption Statement
(40 CFR 152.85, 4/85)

D. Certification with Respect to Citation of Data
(April, 1985)

E. Five (5) copies each of the prototype lables.

Volume II - Product Chemistry Studies
(Guideline 158.20)

A. 61-2 Manufacturing Procedure

Volume III - Product Efficacy Evaluation
(Guideline 158.160)

A. Evaluation of d-CON^{R}
Ready Mixed Generation II for effectiveness

Volume IV - Brodifacoum Support Data

A. ICI Americas Inc. - February 4, 1988 letter of authorization to reference brodifacoum information in EPA files with the following registration numbers: 10182-28, 10182-29, 10182-48, 10182-25, 10182-38, 10182-39, 10182-40, 10182-41, 10182-61, 10182-60, 10182-75 and 10182-76.

Thank you for your prompt attention to the subject application for registration. Anything you can do to expedite the approval of this application would be greatly appreciated. Should you have any questions whatsoever, please do not hesitate to call me at (201) 573-5846.

Sincerely,

Robert L. Bruns, Director
Product Development

RLB:RF
Enclo.

Evaluation of d-con Ready Mixed

Generation II for Effectiveness - (01)

Pages 317-322 - *Inert ingredient information may be entitled to confidential treatment*

Pages 323-331 - *Confidential Statements of Formula may be entitled to confidential treatment*